



Ein cyf/Our ref: MA-L/VG/0420/19

Dai Lloyd AC
Cadeirydd y Pwyllgor Iechyd, Gofal Cymdeithasol a Chwaraeon
Cynulliad Cenedlaethol Cymru
Bae Caerdydd
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30 Awst 2019

Annwyl Dai,

Bil Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru)

Diolch i chi am eich llythyr dyddiedig 23 Gorffennaf yn nodi'r materion y cytunais roi rhagor o wybodaeth amdanynt yn ystod fy ymddangosiad gerbron y Pwyllgor Iechyd, Gofal Cymdeithasol a Chwaraeon ar 11 Gorffennaf. Mae'n bleser gennyf gynnwys yr wybodaeth ganlynol ynglŷn â'r meysydd hyn, a darparu mwy o eglurder ynghylch nifer o feysydd eraill y cyfeiriwyd atynt yn ystod sesiwn y Pwyllgor. Rwy'n gobeithio y bydd yr wybodaeth o gymorth i'r Pwyllgor gyda'r gwaith craffu sy'n mynd rhagddo.

Mae cynllun Llywodraeth Cymru, sef *Cymru Iachach: Ein Cynllun ar gyfer Iechyd a Gofal Cymdeithasol*, yn amlinellu sut y bydd ansawdd yn allweddol i sicrhau bod y system iechyd a gofal cymdeithasol yng Nghymru yn addas ar gyfer y dyfodol, ac yn gynaliadwy ar gyfer y tymor hir. O ganlyniad, rydym wedi penderfynu mai'r angen i wella ansawdd fydd y cysyniad canolog sy'n sail i ddarpariaethau'r Bil.

Er hynny, nid yw'r darpariaethau sydd wedi'u cynnwys yn y Bil ond yn rhan o'r stori gyfan. Fel yr eglurais wrth y Pwyllgor, rydym wedi mabwysiadu dull gweithredu y mae ei arfer wedi ei hen dderbyn o gynnwys darpariaethau yn y Bil dim ond os nad yw'r pwerau deddfu sylfaenol sy'n bodoli ar y pryd yn ddigon i'n galluogi i gyflawni bwriad y polisi. Felly, dylid edrych ar y camau, yr ydym ni fel Llywodraeth yn eu cymryd i wella ansawdd gwasanaethau, fel pecyn o fesurau sy'n cael eu rhoi ar waith mewn deddfwriaeth sylfaenol, is-ddeddfwriaeth, cyfarwyddydau, a chanllawiau.

Yn y Papur Gwyn, *Gwasanaethau sy'n Addas i'r Dyfodol, Ansawdd a Llywodraethiant ym maes Iechyd a Gofal yng Nghymru*, ymgynghorwyd ar nifer o gynigion y mae gwella ansawdd yn ganolog iddynt. Mae **Atodiad 1** yn nodi'r gwaith sy'n mynd rhagddo i weithredu'r cynigion nad ydynt yn ymddangos ar wyneb y Bil gan ein bod yn gallu defnyddio

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

ein pwerau presennol i sicrhau'r newid angenrheidiol. Yr eithriadau i hyn fydd unrhyw newidiadau sylfaenol i'r fframwaith deddfwriaethol sy'n sail i waith Arolygiaeth Gofal Iechyd Cymru.

Darpariaethau'r Bil

Dyletswydd Ansawdd

Gan droi at y darpariaethau yn y Bil, mae'r Memorandwm Esboniadol yn disgrifio'r dystiolaeth o blaid cyflwyno dyletswydd ansawdd newydd ehangach¹ a'r manteision a ddaw i unigolion, gweithwyr gofal iechyd proffesiynol, a chyrrff y GIG² yn sgil gweithredu'r ddyletswydd newydd honno. Drwy wella ansawdd, daw manteision i gleifion fel poblogaeth ac fel unigolion.

Fel y trafodwyd, mae'r ddyletswydd newydd yn ehangach ei chwmpas ac yn wahanol ei natur i'r ddyletswydd ansawdd bresennol yn Neddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2003. Mae'r ddyletswydd newydd yn mynd y tu hwnt i ffocws y ddyletswydd bresennol ar safonau gwasanaeth ac ansawdd y gwasanaethau a ddarperir i'r unigolyn, sydd braidd yn gul. O ran materion iechyd, bydd yn gofyn i gyrff y GIG a Gweinidogion Cymru arfer eu swyddogaethau mewn modd penodol, gan y bydd yn rhaid iddynt ystyried sut y gallant wella ansawdd gwasanaethau iechyd wrth wneud eu holl benderfyniadau. Drwy ddefnyddio'r dull gweithredu hwn, daw ystyriaethau gwella ansawdd yn rhan annatod o'u prosesau penderfynu.

Fel yr eglurwyd wrth y Pwyllgor, bydd gofyn i'r cyrff sy'n ddarostyngedig i'r ddyletswydd gydymffurfio â hi mewn modd sy'n ymwneud â'r system gyfan, yn seiliedig ar y diffiniad rhyngwladol, sy'n nodi chwe pharth³ ar gyfer ansawdd gofal iechyd a gafodd eu cynnig gan y Sefydliad Meddygaeth.

Fel yr wyf wedi dweud wrth y Pwyllgor, rydym yn bwriadu llunio canllawiau i helpu cyrrff y GIG i weithredu'r ddyletswydd hon. Bydd natur y canllawiau hyn yn debyg mewn llawer ffordd i'r rhai a luniwyd i helpu i weithredu Deddf Llesiant Cenedlaethau'r Dyfodol (Cymru) 2015. Er enghraifft, byddant yn cynnwys cyfres o astudiaethau achos i ddangos sut y gallai cyrrff y GIG ddangos eu bod wedi defnyddio'r egwyddorion ansawdd er mwyn sicrhau gwelliant. Amgaeir amlinelliad drafft o'r canllawiau yn **Atodiad 2**.

Dyletswydd gonestrwydd

Bydd y ddyletswydd gonestrwydd yn adeiladu ar y gwaith y mae Llywodraeth Cymru a GIG Cymru wedi ei gyflawni eisoes i sicrhau bod y rheini sy'n darparu gwasanaethau'r GIG yn gweithredu mewn modd agored a gonest pan fo rhywbeth yn mynd o'i le, ac y byddant yn cefnogi'r camau a gymerir i weithredu system sy'n seiliedig ar ddysgu a gwella.

Yn y Memorandwm Esboniadol, rydym wedi egluro pam fod angen dyletswydd gonestrwydd sefydliadol, ynghyd â'r amcanion polisi yr ydym yn awyddus i'w cyflawni drwy ei chyflwyno, a diben y ddeddfwriaeth⁴. Mae tystiolaeth yn dangos bod gweithredu mewn modd mwy

¹ Gweler tudalennau 10-16 a 50-51.

² Gweler tudalennau 66-67.

³ Gweler tudalen 11.

⁴ Gweler tudalennau 17-23.

agored, tryloyw, a gonest yn gysylltiedig â darparu gwasanaethau iechyd a gofal cymdeithasol o ansawdd uwch⁵. Fodd bynnag, mae hefyd ystyriaethau dynol pur y tu ôl i'm penderfyniad i gyflwyno'r ddyletswydd hon. Rydym yn gwybod bod mwyafrif llethol y darparwyr ym meysydd iechyd a gofal cymdeithasol yn awyddus i ddarparu gwasanaethau o ansawdd uchel sy'n ddiogel ac sy'n arfer caredigrwydd wrth ymwneud â'r claf. Fodd bynnag, rydym yn ymwybodol ar yr un pryd y gallai rhywbeth weithiau mynd o'i le; a bod hyn yn digwydd o bryd i'w gilydd er gwaethaf y bwriad i'r gwrthwyneb; a hefyd bod pobl weithiau'n cael eu niweidio o ganlyniad.

Ym meysydd iechyd a gofal cymdeithasol, mae gan ddefnyddiwr y gwasanaethau berthynas barhaus â'r sawl sy'n darparu ei ofal a'i driniaeth. Mae ffordd y darparwr o ymateb pan fo rhywbeth yn mynd o'i le yn gallu cael effaith enfawr ar ansawdd y berthynas hanfodol sydd rhyngddo a'r claf, ac ar ymddiriedaeth y defnyddiwr yn y sefydliad. Drwy roi dyletswydd gonestrwydd ar ddarparwyr y GIG, bydd yn bosibl cryfhau ac ehangu'r fframwaith ar gyfer rhoi gwybodaeth i'r unigolyn a'i gynorthwyo os bydd rhywbeth wedi mynd o'i le, a bydd hynny'n helpu i gynnal yr integriti sy'n rhan hanfodol o'r berthynas rhwng y darparwr a'r claf.

Rwyf eisoes wedi rhoi Datganiad o Fwriad y Polisi i'r Pwyllgor ar gyfer y rheoliadau sy'n ofynnol yn adran 4 o'r Bil, a fydd yn gosod gweithdrefn y ddyletswydd gonestrwydd⁶:

Yn ogystal â hyn, amgaeir amlinelliad drafft o'r canllawiau statudol yn **Atodiad 3**, sef canllawiau a fydd yn cael eu datblygu a'u chyhoeddi i helpu i gyflwyno'r ddyletswydd. Cynhelir ymgynghoriad ar y rheoliadau, a bydd y Cynulliad yn craffu arnynt. Caiff y gwaith ei ddatblygu gyda chymorth gweithgor a fydd yn cynnwys clinigwyr, a gweithwyr proffesiynol perthnasol eraill, yn ogystal â chynrychiolwyr lleyg.

Hefyd yn **Atodiad 4**, rwyf wedi disgrifio hynt y ddyletswydd yn Lloegr, yn yr Alban, ac yn y maes gofal cymdeithasol yma yng Nghymru. Mae hyn yn cynnwys y rhesymeg y tu ôl i'r dull gweithredu a fabwysiedir yn y Bil.

Sanctsiynau

Yn sesiynau'r Pwyllgor hyd yn hyn, rydym hefyd wedi trafod pam nad wyf yn cynnig cyflwyno trefniadau gweithredu sanctsiynau pwrpasol i gefnogi'r dyletswyddau ansawdd a gonestrwydd. Y rheswm y tu ôl i'r penderfyniad hwn yw ein nod o greu diwylliant lle y mae gwella ansawdd, ac ethos o fod yn agored a thryloyw a mynd ati i ddysgu a gwella, yn sylfaenol bwysig. Rwyf o blaid rhoi pwyslais ar greu'r amgylchedd iawn ar gyfer newid, a'r systemau arweinyddiaeth priodol, sy'n ehangach na dim ond cymhellion ariannol a sanctsiynau llym. Bydd yr adroddiadau blynyddol gorfodol, a fydd yn dweud sut mae cyrff a darparwyr y GIG wedi ymateb i'r dyletswyddau, yn ychwanegu at y ffynonellau gwybodaeth, sy'n bodoli eisoes, ac a ddefnyddir gan Swyddfa Archwilio Cymru ac Arolygiaeth Gofal Iechyd Cymru i asesu ansawdd y gwasanaethau a ddarperir a sut maent yn cael eu

⁵ Sefydliad Iechyd y Byd, y Sefydliad ar gyfer Cydweithrediad a Datblygiad Economaidd, a Banc y Byd. *Delivering quality health services: a global imperative for universal health coverage*. [Rhyngwryd]. Geneva; 2018. Ar gael o:

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

Yr Adran Iechyd a Gofal Cymdeithasol a'r Gwir Anrh. Jeremy Hunt AS. *Good care costs less* [Rhyngwryd]. Ar GOV.UK. 2014 [dyfynnwyd 1 Ebrill 2019]. Ar gael o:

<https://www.gov.uk/government/speeches/good-care-costs-less>

⁶<http://www.senedd.cynulliad.cymru/documents/s90279/Datganiad%20o%20Fwriad%20y%20Polisi.pdf>

llywodraethu. Bydd unrhyw bryderon yn cael eu codi a'u hystyried o dan Drefniadau Uwchgyfeirio ac Ymyrryd y GIG.

Yn y cyd-destun ehangach, un o'r camau gweithredu yn y cynllun *Cymru Iachach* yw cyflwyno cyfres o ddulliau i sicrhau newid. Mae'r rhain yn cael eu datblygu gyda'r nod o greu'r amodau i newid systemau ac ymddygiad.

Mae adroddiad Canolfan Polisi Cyhoeddus Cymru, 'Cefnogi Gwelliannau mewn Byrddau Iechyd'⁷, a gyhoeddwyd ym mis Ebrill 2019, yn cydnabod bod angen i fyrddau iechyd ddefnyddio dull gweithredu sy'n rhoi sylw i'r system gyfan er mwyn gwella perfformiad (yn ei ystyr ehangach), gyda chymorth amodau ac amgylchedd sy'n gallu hwyluso'r gwaith o sicrhau newid.

Bydd y dysgu sy'n deillio o'r adroddiad yn cael ei ystyried wrth i'r cynigion ar gyfer sicrhau newid esblygu a chael eu gweithredu ochr yn ochr â sefydlu Gweithrediaeth y GIG.

Corff Llais y Dinesydd

O ran darpariaethau ar gyfer Corff Llais y Dinesydd, treuliyd amser yn y Pwyllgor yn ystyried strwythur presennol Bwrdd y Cynghorau Iechyd Cymuned yng Nghymru, penodiadau i'r Bwrdd, a sut mae aelodau gwirfoddol yn cael eu penodi i Gynghorau Iechyd Cymuned lleol. Gwnaed cymariaethau a gofynnwyd cwestiynau ynghylch sut y byddai aelodau Bwrdd corff arfaethedig newydd Llais y Dinesydd yn cael eu penodi, a pha drefniadau a fydd ar waith i recriwtio aelodau gwirfoddol. Mae **Atodiad 5** yn crynhoi'r trefniadau presennol ar gyfer y Cynghorau Iechyd Cymuned, a'r rhai a gynigir ar gyfer Corff Llais y Dinesydd.

Hefyd, fel rhan o'n hymrwymiad i egluro wrth y Pwyllgor ba ganllawiau yr ydym yn bwriadu eu cyhoeddi, yn **Atodiad 6** amgaeaf amlinelliad drafft o'm prif ddisgwyliadau o ran sut y bydd Corff Llais y Dinesydd yn gweithredu. Mae'r amlinelliad hwnnw'n ystyried yn llawn y ffaith y bydd y corff newydd, oherwydd natur y swyddogaethau y bydd yn eu cyflawni, yn gweithredu'n annibynnol ar Lywodraeth Cymru.

Amserlenni gweithredu

Os caiff ei basio, disgwyliar i'r Bil gael Cydsyniad Brenhinol ym mis Ebrill 2020.

Fel y nodwyd yn yr Asesiad Effaith Rheoleiddiol, rydym yn bwriadu cychwyn y darpariaethau ar gyfer dod â'r ddyletswydd ansawdd newydd i rym yn yr haf 2021. Bydd hyn yn rhoi digon o amser inni sicrhau bod y canllawiau a amlinellir yn Atodiad 2 yn cael eu datblygu mewn partneriaeth; eu bod yn addas ar gyfer eu diben; a bod yr holl staff wedi cwblhau'r hyfforddiant y mae ei angen i weithredu'r ddyletswydd yn llwyddiannus. Ein bwriad hefyd yw cychwyn y pŵer i benodi Is-gadeiryddion ar Ymddiriedolaethau'r GIG yr adeg honno.

O ran y ddyletswydd gonestrwydd, rydym yn gweithio tuag at ddyddiad cychwyn yng ngwanwyn 2022. Cyn y gallwn ddod â'r ddyletswydd i rym, byddwn yn paratoi rheoliadau'r

⁷ <https://www.wcpp.org.uk/wp-content/uploads/2019/04/Supporting-improvements-in-health-boards.pdf>

weithdrefn gonestrwydd, ac fel yr eglurir yn Atodiad 3, byddwn hefyd yn gwneud y gwelliannau angenrheidiol i reoliadau presennol Gweithio i Wella. Unwaith yn rhagor, bydd angen inni sicrhau bod yr holl staff yn cwblhau'r hyfforddiant angenrheidiol, a bod y canllawiau statudol wedi cyrraedd eu fersiwn derfynol, cyn cychwyn y darpariaethau hyn. Fel y dywedwyd eisoes yn y Memorandwm Esboniadol, ein bwriad polisi yw dwyn ymlaen reoliadau o dan Ddeddf Safonau Gofal 2000 i osod dyletswydd gonestrwydd ar ddarparwyr gofal iechyd annibynnol rheoleiddiedig yng Nghymru. Byddwn yn ymgynghori ar y rhain hefyd, a'r bwriad yw dod â nhw i rym ar yr un pryd â'r darpariaethau gonestrwydd yn y Bil.

O ran Corff Llais y Dinesydd, y bwriad yw sefydlu'r corff newydd fel y daw i effaith gweithredol o fis Hydref 2021. Fel sy'n digwydd pan fydd unrhyw gorff newydd yn cael ei sefydlu, bydd yn cymryd amser i ymgysylltu â staff ynglŷn â throsglwyddiadau staff, cael hyd i lety priodol, a dilyn y broses gaffael briodol ar gyfer contractau, gan gynnwys rhai ar gyfer TGCh a gwasanaethau.

Edrychaf ymlaen at ddarparu tystiolaeth bellach i'r Pwyllgor maes o law.

Rwy'n anfon copi o'r llythyr hwn at Gadeiryddion y Pwyllgor Cyllid a'r Pwyllgor Materion Cyfansoddiadol a Deddfwriaethol.

Yn gywir,

A handwritten signature in black ink that reads "Vaughan Gething". The signature is written in a cursive, flowing style.

Vaughan Gething AC / AM
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Areas consulted on in the White Paper but not brought forward in the Bill	How will this be taken forward?
Health board membership and composition; and the role of the board secretary	<p>Health Boards and NHS Trusts are now operating in a different landscape to when they were first established. The long term plan - “A Healthier Wales” looks to bolster and reinforce the existing planning (IMTP) system, but advocates for a transformation in the way health and care services are delivered in Wales. Legislation such as the Well-being of Future Generations 2015 has also set the path for a shift in the way services are delivered in Wales and NHS Boards must be organised in such a way they can most effectively meet future challenges.</p> <p>Changes to NHS Board membership and composition will require amendment to existing regulations and establishment orders. Board structures should reflect organisational structures which, in turn, should reflect what and how health and care services are provided for and accessed by patients. Any changes to board structures, however, should be managed carefully, so not to compound issues we are looking to remedy. Therefore, changes to overall board size and composition of NHS bodies needs to be considered within the wider context and systems. Further policy work is being undertaken on this basis with the purpose of developing a series of options for consideration and discussion with partner organisations. We want to progress with involving and engaging key stakeholders in the development of policy on future proposals. We can consider then what we need to do, if anything, about the membership and composition of boards, with a view to taking forward any required changes to secondary legislation by Spring 2021. Any changes to the regulations will be subject to a separate Explanatory Memorandum and Regulatory Impact Assessment and consultation.</p> <p>With regard to NHS Board Secretaries, the role of the Board Secretary is crucial to the ongoing development and maintenance of a strong governance framework within boards and is a key source of advice and support to the Chair and other board members. The Board Secretary acts as the guardian of good governance. We are investigating, through engagement with the NHS, how Model Standing Orders may be amended to provide a clearer role for the Board Secretary, support the integrity of the role and prevent the role from being compromised. We are taking this work forward with a view to introducing any changes in 2020/21.</p>
Reform of the Inspectorates/ Healthcare regulation and inspection; and	We want to ensure the system of regulation and inspection across health and social services is aligned and future-proofed in order to provide the relevant assurances to support improvement within organisations from a person-centred perspective. There should be a consistent approach to inspection and to examining the quality and safety of services received. People expect the

<p>common standards</p>	<p>inspectorates to work together where health and care services overlap.</p> <p>Work has begun to scope the legislative requirements mapping out the regulatory gaps and considering the type of inspectorate / regulator needed; whether light touch/compliance-focussed/supports improvement etc. and how the context will align to A Healthier Wales and proposals for integration and the new citizen voice body. To ensure the legislative framework is fit for purpose and will meet the need of continually evolving healthcare service provision, it was determined that this area would be considered separately.</p> <p>In the interim, we intend to utilise existing powers to incrementally develop HIW's capacity and capabilities, to achieve a more sustainable position, allowing it to be ready to respond to any future new legislative framework. Work is already underway to enable this and further proposals, when developed, will be subject to full consultation.</p> <p>As part of this we can again consider whether HIW should be established as an independent body and indeed whether it should merge with CIW, to further support the integration of health and social care.</p>
<p>Joint complaints handling</p>	<p>The consultation on the White Paper indicated that there was some support for the idea of joint investigations, but many respondents appeared not to have grasped the proposal related to complaints that span health <u>and</u> social care.</p> <p>Officials will be further engaging with NHS Wales organisations, local government and other bodies to discuss ways of making the process simpler for people who have complaints that span both areas.</p> <p>In particular, consideration will be given to utilising existing legislative powers to enable a person who wishes to make a complaint about health and social services matters to only have to make one complaint to trigger both procedures.</p>
<p>Service change</p>	<p>In the area of service change, further work determined that proposals can be delivered under existing powers using a mixture of guidance and ministerial directions.</p> <p>The current guidance needs fundamental change to ensure it is fit for the future. The new service change policy needs to work in the context of the changing legislative landscape, including the Well-being of Future Generations (Wales) Act 2015, and the Bill provisions on quality and the replacement of the CHCs with the new Citizen Voice Body. It will also need to be framed to take account of the recommendations of the Parliamentary Review of Health and Social Care and the Welsh Government's response to those recommendations in "A Healthier Wales".</p> <p>The intention is to bring new guidance into force to coincide with the establishment of the new Citizen Voice Body in Autumn 2021.</p>

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

DRAFT OUTLINE: GUIDANCE ON THE DUTY OF QUALITY FOR NHS BODIES

Background

The Health and Social Care (Quality & Engagement) (Wales) Bill (“the Bill”) includes a duty of quality (“the duty”) that requires NHS bodies – local health boards, NHS Trusts and special health authorities – in Wales to exercise their functions view to securing improvement in the quality of health services.

This includes, but is not limited to:

- (a) the effectiveness of health services;
- (b) the safety of health services; and
- (c) the experience of individuals to whom health services are provided.

In order to comply with the duty, NHS bodies will need to demonstrate that they are outcome focused when making decisions across their functions and, as part of the reporting process mandated within the Bill, will have to assess the extent to which they have led to an improvement in outcomes. This means that NHS bodies will have to be able to evidence how the actions they have taken have resulted in improved outcomes for service users.

This aims to ensure a whole system approach to quality, replacing the current duty within Section 45(1) of the Health and Social Care (Community Health and Standards) Act 2003 which has been too narrowly interpreted as simply relating to clinical services and putting assurance (control) arrangements in place to monitor these.

Enacting this broader duty of quality, more in keeping with how we now want NHS bodies to work, will strengthen actions and decision making to drive improvements in quality that will focus on the outcomes for the people of Wales.

Welsh Ministers will also be under this duty in respect of their health related functions.

This document sets out a draft outline for those areas we would expect the guidance for NHS bodies to cover.

Whilst the primary audience of this guidance will be those to whom it will apply, i.e. all staff within NHS bodies, including Board Members, its development will be informed by the views of, and it will be written in such a way as to be understood by, service users (and the wider public).

Introduction

This section will set the overall context for the new duty and how it is a key lever in helping realise the expectations and vision set out in *A Healthier Wales* and its key emphasis on driving change and improvement. Notably a whole system approach that will be equitable, delivering the same high quality of care and achieving more equal outcomes for everyone in Wales.

It will particularly describe the overall quality framework that bodies must have in place to help achieve and evidence this: quality planning, improvement and control (assurance).

In order for NHS bodies to act in the desired way there needs to be a clear understanding of the duty. This involves understanding that the new duty is broader than the current duty in the 2003 Act and more in keeping with how we now want NHS bodies to work. This will strengthen actions and decision making to drive improvements in quality.

This section would specifically provide:

- an overview of the duty;
- an explanation as to why the duty is being introduced and the key policy objectives, including how it helps to achieve a system-wide focus on quality and continuous improvement;
- a high level overview of how the duty builds on the existing quality assurance infrastructure within the Welsh NHS;
- how it is intended the duty would form part of the Welsh Government's wider and continuous approach towards a health and social care system that is always striving to secure improvement in the quality of services, and therefore outcomes for service users; and
- how it supports the five ways of working under the Well-being of Future Generations (Wales) Act 2015, by encouraging long-term thinking and collaborative action.

Aim of the guidance

This section would explain the aims and purpose of the guidance. It would include detail on:

- how the Bill (Act) and guidance should be read together, to fully understand the expectations of the duty;
- how implementation of the duty should be supported by training and processes within NHS bodies; and
- how the guidance has been developed in partnership with clinicians, patients and members of the public, so as to contain illustrative examples and case studies and to ensure it is clear and capable of being understood by all.

It would also address the key implementation issues which may be experienced as a result of the introduction of the new duty, including learning from other parts of the UK (where comparable), and would provide good practice case studies where appropriate.

Finally, it could also include information about how the guidance will be reviewed and updated.

Understanding the meaning of 'quality'

This section would further describe what is meant by 'quality' as to ensure the intent of the Bill is fully understood, in a practical sense.

This would need to cover details on:

- the definition of quality in the context of the duty i.e. the internationally accepted

definition embracing six domains: safe, effective, person centred, equitable, efficient and timely.

- how it should apply i.e. to whole processes and across all functions of an NHS body, within the context of the health and well-being needs of their populations;
- what it means for considerations and decisions made by Boards, as well as what it means for frontline staff in their day to day work; and
- how the new duty is broader in scope and different in nature to the current duty of quality in Section 45 of the Health and Social Care (Community Health and Standards) Act 2003.

How will the duty work in practice?

The new duty will require NHS 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. This section would provide supporting detail on how the duty is intended to work in practice.

It will provide details on:

- how the quality of all services should be considered at a wider population level – embedding quality considerations at the heart of decision-making processes;
- how broadening the consideration of quality will encourage bodies to:
 - work with their neighbouring health boards and cross-sector partners to reduce unwarranted variation and health inequality, including tackling inequity within its open population and working with partners to address this; and
 - promote the sharing of resources and expertise which will in turn unlock more opportunities to improve the effectiveness, safety and quality of services.
- the need for NHS bodies to become much more outcome-focused when making decisions and to think in a different way when considering what steps they will take to secure improvements in services – including how they deliver improvements which create services that influence the whole life course, improving health and well-being outcomes, reducing health inequalities and ultimately reducing demand on statutory services;
- how the duty applies to NHS bodies that do not directly provide clinical services – reflecting the impact that improvements in the quality of health services can be achieved through improvements to backroom services, such as procurement processes or ICT capability; and
- how it is expected that NHS bodies should include within local commissioning arrangements the need for data on quality/outcomes from their providers.

It will also illustrate how complying with the duty will contribute to and influence the existing quality assurance infrastructure and inform quality planning and improvement priorities.

This should inform:

- progress towards the national objectives associated with the Well-being of Future Generations (Wales) Act 2015;
- NHS bodies' own Quality and Safety Committees and Board meetings;
- the annual NHS planning process - Integrated Medium Term Plans (IMTPs);
- progress against the NHS delivery and outcome framework requirements; and
- compliance with health and care standards and relevant guidance, set by the Welsh Ministers.

Finally, this section will also need to provide illustrative examples and case studies around how organisations could apply the principles of duty in order to secure improvement. For example a visible difference will be within Board and Committee papers and minutes, as decisions made by NHS bodies will be clearly documented so as to demonstrate how they are being informed by service improvement considerations. This will help contextualise and reinforce any learning points.

The duty to report

The reporting requirements represent a considerable step forward, as the existing duty has no such reporting requirement, and should be seen as an important lever in further increasing transparency and accountability of NHS bodies in regard to their decisions, identified priorities and the allocation of resources to do so. It is an important mechanism in helping to address the findings of the OECD quality review in 2016 where they concluded that LHBs were showing less innovation and fewer radical approaches to system change and quality improvement than might have been expected.

The reports will need to make explicit how the delivery of the duty has led and will continue to lead to improvements in quality - including an assessment of the extent of any improvement in quality outcomes including the effectiveness and safety of services, along with the patient experience, achieved during the reporting period. This will also enable improvements in quality to be monitored over time with milestones set as required where improvements are likely to a number of years to secure the anticipated improvements in outcomes.

This section would therefore provide guidance on how NHS bodies can demonstrate they have complied with the duty via their annual quality reports, mandated in the Bill. This section will therefore provide details on:

- the timescale for the reports to be produced and how and where they should be published;
- the format in which the reports should be published;
- further details on the expected content of the report, for example, including how key decisions and actions taken within the reporting period have led to service improvements and better outcomes and how the NHS body intends to secure improvement in identified areas over the next year (or more); and
- how NHS bodies should record, maintain and monitor improvements in services and outcomes so as to be able to reference robust evidence in demonstrating how they have complied with the duty and secured improvements in outcomes for service users.

This section would also explain how the new reports will replace and build on the current Annual Quality Statements, to reflect that the new reports will become a whole system document – one which has a wider focus and greater rounded evidence to demonstrate quality improvement across an organisation and in some cases across organisational boundaries, where the provision of services are arranged through other NHS bodies within Wales.

Staff training and support

Moving 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. The Explanatory Memorandum at paragraphs 180-189 detail a range of training and resources to embed these new ways of working at all levels. This section would outline our expectations of NHS bodies in relation to changes required, including signposting training and support for staff in respect of the duty.

It may also provide an overview of what NHS bodies should consider when developing any local policies to support the duty.

FAQs

This section would set out a series of anticipated common questions, supported by answers. It could also reference any training or additional information for further learning.

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

DRAFT OUTLINE: STATUTORY GUIDANCE ON THE DUTY OF CANDOUR

Background

The Health and Social Care (Quality & Engagement) (Wales) Bill (“the Bill”) includes the power to make regulations which detail the process to be followed by NHS bodies when the duty of candour has been triggered. The regulations, which will be the subject of public consultation, will be supported by statutory guidance.

The intention is to convene a working party made up of clinicians (representing primary, secondary care) and service user representatives to collaborate in the development of the statutory guidance to ensure it is complete, relevant, clear and accessible to the service and the public.

Evidence demonstrates that increased openness, transparency and candour are linked with the delivery of higher quality health and social care. It shows 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.

For patients, when something goes wrong, the majority of individuals and their loved ones want to be told honestly what happened, receive appropriate after-treatment care and support, be reassured that everything is being done to learn from what went wrong and trust that the same thing won't happen again. The duty of candour will help achieve this.

The proposed duty of candour will require NHS bodies to follow a set process when an adverse outcome occurs and the duty is triggered. The duty is placed at organisational level which will help create the conditions for health professionals to discharge their professional duties of candour by ensuring they have support of the organisation they work for. In order for organisations to meet the obligations placed on them in the Bill, all staff will need to act in a way that complies with the duty. All NHS bodies will need to have comprehensive policies and procedures in place to enable staff to do so effectively.

This document sets out a draft outline for those areas we would expect the statutory guidance to cover.

Introduction

In order to create a whole system approach to candour; encourage organisational learning; encourage staff to speak openly about concerns and to support NHS bodies to build on the work underpinned by Putting Things Right¹, there must be a fundamental understanding of the intent behind the duty of candour. Therefore, this section of the guidance would seek to set out the legislative framework and explain the policy intent behind the duty in a straight forward and accessible way.

¹ 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>

This section would provide:

- an overview of the duty of candour (“the duty”) within the Bill and the supporting regulations which set out the procedure to be followed when the duty is triggered;
- how it is intended the duty would form part of the Welsh Government's wider and continuing approach towards a health and social care system that is always listening, learning and improving - which has the trust and confidence of service users and their families;
- an explanation as to why the duty is being introduced and the key policy objectives, including how it helps to achieve a system-wide approach to being open and honest when things go wrong;
- details of how the duty builds on the “Being Open” principles that are embedded within the existing Putting Things Right arrangements (which set out process for managing concerns, including complaints and serious incidents within NHS Wales); and
- how the guidance has been co-produced with clinicians and patient representatives and contains illustrative examples and case studies to ensure it is clear and able to be understood by all.

This section would also explain that the duty is ultimately to serve service users 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, and separately to ensure organisational learning.

It would also underline the importance of ensuring staff who have provided treatment that has triggered the duty can also receive support from their employer.

The new duty aims to foster and promote a culture of openness and learning within NHS organisations. It is not about preventing bullying, victimization or harassment, nor is it about protecting whistleblowers. The law, guidance and best practice in relation to these matters are dealt with in separate legislation and within existing NHS processes and procedures. However, it is anticipated the duty will make it easier for individual staff members to be open and honest with service users when things go wrong and to receive support to enable this.

Aim of the guidance

This section would explain the aims and purpose of the guidance. It would also explain that, in accordance with section 10 of the Bill, when exercising any functions connected with the duty of candour, an NHS body must have regard to guidance issued by the Welsh Ministers.

This section would explain how the guidance aims to provide a framework of best practice that would assist providers of NHS services in the implementation of the duty. It would seek to guide NHS providers to develop local policies, guidance and procedures to support local implementation of the duty in a manner that is tailored to the particular services they provide. Ultimately being open with patients and their representatives, when things go wrong, should feel like the right thing to do.

It would also address the key implementation issues which may be experienced as a result of the introduction of the new duty, including learning from other parts of the UK, and would provide good practice case studies where appropriate.

This section will include detail on:

- how the guidance and regulations have been developed in collaboration with the Wales Partnership Forum (which is made up of representatives from the NHS workforce, employers and Welsh Government) and Trade Union engagement with a view to it being used as an 'All-Wales model' in support of a consistent approach throughout health board areas;
- how the Act, regulations and guidance should be read together, and how the duty will be aligned with the Putting Things Right arrangements; and
- how the duty is designed to create an environment that is supportive of staff with concerns, feeling able to raise these with their employer and be sure they would not suffer any detriment as a result of voicing those concerns.

It could also include information about how the guidance would be reviewed and updated.

Finally, it will explain how the duty is separate from the All Wales Staff Raising Concerns (Whistleblowing) Policy², which is in place in every Local Health Board and NHS Trust in Wales.

Trigger for the duty

The Bill sets out two conditions which must be met for the duty to be triggered:

- the person to whom health care is being or has been provided by a NHS body has suffered an adverse outcome; and
- the health care was or may have been a factor in the service user suffering that outcome.

A service user is to be treated as having suffered an adverse outcome if he or she experiences or the circumstances are such that he or she could experience any unexpected or unintended harm that is more than minimal.

The guidance would provide clarity on the range of circumstances under which the duty can be triggered and what this would mean for the people to whom the duty applies.

We have pursued a deliberate policy of not defining what "more than minimal" harm means on the face of the Bill or in regulations. Instead, we have learned from the experience of England and Scotland where attempts were made in legislation to define the thresholds of harm needed to trigger their duties. We intend to define what is meant by more than minimal harm in the guidance.

² NHS Confederation employment policy and procedures [Internet]. [Cited 25 July 2019]. Available from: <https://www.nhsconfed.org/regions-and-eu/welsh-nhs-confederation/nhs-wales-employers/our-work/employment-policy-and-procedures>

There are a number of reasons for this. Firstly we think it is right the threshold that triggers the duty should be developed with the assistance of a working group comprised of clinicians and service users. Secondly, the description of 'more than minimal harm' is complex due to the range and nature of care provided across the NHS. It is possible to provide a much more meaningful definition, backed by illustrative examples and case studies, in guidance. The key aim is to ensure the definition is fit for purpose across all NHS settings, assists in the successful implementation of the duty and is accessible to service users and clinicians. Ultimately it is to promote a culture of openness and honesty with services users and enable staff to focus on learning and improvement.

It is expected the threshold would be developed having regard to existing definitions of harm currently in use in the NHS in Wales such as those used in the National Reporting and Learning System³ (the system for reporting patient safety incidents in England and Wales), or if applicable, its successor system.

It is also intended that the guidance will provide worked examples of cases where the duty will be triggered. The intention here is to provide a range of examples from the obvious through to scenarios where the application of the duty is, perhaps, less obvious. Here, for example, the guidance will make it clear the duty is triggered not only when more than minimal harm is known to have occurred but in cases where such harm might occur in the future. Two examples may include:

- If a person suffers a fall and a fracture is not identified on the x-ray while in A&E, but is identified on a review of the x-ray a week later. In this case the duty of candour would be triggered at the point at which the body becomes aware the x-ray results showed a fracture not when it is known whether the patient has suffered harm from the failure to make a timely diagnosis. A person suffers an adverse outcome if that person suffers more than minimal harm or the circumstances are such that the person could experience any unintended or unexpected harm that is more than minimal. Clearly in the example mentioned there is potential for the delay in treatment to have caused more than minimal harm that was unintended or unexpected and so the duty is triggered.
- An error in the administration of medication on discharge may not result in a patient suffering immediate harm. However the duty of candour would be triggered at the point at which the body becomes aware of the error not when they become aware of any harm being suffered by the patient. Again this is because a medication error, unless it is very minor, clearly has the potential to cause unexpected or unintended harm that is more than minimal.

This section could also address some of the particular circumstances that may arise in triggering the duty, and how the NHS body should deal with them, such as:

- if the adverse outcome triggering the duty is brought to the attention of the NHS provider by the patient or their family member/advocate;
- the case is 'borderline' and a judgement is required as to whether the threshold has been met, and the duty triggered;
- where there is more than one NHS provider involved in an incident;

³ Patient safety Welsh Government services and information [Internet]. GOV.WALES. 2019 [cited 25 July 2019]. Available from: <https://gov.wales/patient-safety>

- where more than one incident or a chain of events has occurred;

Finally, the guidance would need to provide detail on when the duty will not be triggered. Such instances would include:

- when a near miss has occurred. A “near miss” is an event that might have resulted in more than minimal harm to the patient but the error that would have caused the harm is noticed and rectified before harm can be caused. By their very definition, near misses are not covered by the duty of candour as there is no potential for any harm to be caused to the patient. However, it is important to learn from near misses and the guidance will clearly signpost the action that NHS bodies need to take to respond to and learn from near misses to prevent recurrence; or
- when harm occurs as a result of the medical condition itself and is solely attributable to the person’s underlying illness or condition.

Notification

It is commonly recognised that when things go wrong, patients and their families expect three things:

- be told honestly what happened;
- to know what would be done to deal with the harm caused; and,
- to know what would be done to prevent the same thing happening again.

These expectations are the cornerstone of the duty of candour and form the basis underpinning the ‘candour procedure’ which would be set out in regulations. It is expected the regulations would set out detail such as the form, content and timing of the notification, such as:

- the timescale for the notification to be given;
- how the notification should be provided;
- detail of what should be included e.g. that the duty has come into effect and what this means;
- the identity of the ‘nominated individual’ who will be the service user’s point of contact in respect of the notification;
- detail of any further enquiries or reviews to be carried out by an NHS provider in respect of the circumstances in which the duty came into effect;
- the need to keep records; and
- the requirement to report annually on the discharge of the duty.

In support of these regulations, it is expected the guidance would provide further supporting detail on how the duty is aligned with other processes, such as the Serious Incident Framework contained within the Putting Things Right guidance⁴.

It is also expected that the guidance will need to cover how the notification element of the duty works in practice. This may include detail on apologising and where a service user or their representative can obtain further information, for example:

⁴ Putting Things Right guidance [Internet]. Putting things right. 2018 [cited 4 April 2019]. Available from: <http://www.wales.nhs.uk/sitesplus/documents/861/Healthcare%20Quality%20-%20Guidance%20-%20Dealing%20with%20concerns%20about%20the%20NHS%20-%20Version%203%20-%20CLEAN%20VERSION%20-%2020140122.pdf>

- apologising - what an apology means in the context of the duty, when to apologise and how to deliver a meaningful apology; and
- further enquiries – the need to offer the service user, or their representative, the opportunity to express their views, for example considering any questions they would wish to have answered through a review of the circumstances.

It will also include detail on the types of records which should be kept.

It may also address some of the particular circumstances that may arise during the notification process:

- the identification of an appropriate representative for notification purposes (“notified individual”) in cases where this is not the service user themselves e.g.:
 - where the service user is a child or lacks mental capacity;
 - where a provider is unable to contact the service user;
 - where the service user does not wish to be contacted; and
 - where the service user has died.
- best practice advice on determining who should be the nominated point of contact for the NHS provider. They would be responsible for ongoing communication with the service user or their representative:
 - including where more than one NHS provider is involved in an event – namely that a single nominated individual should act on behalf of all relevant organisations
 - situations where it may be deemed reasonable or necessary for Local Health Boards to provide support and assistance to, primary care providers to help them discharge the duty.
- if other than the nominated point of contact, determining who is the appropriate person to notify the individual of the triggering of the duty – this may involve:
 - consideration of the nature of the incident;
 - their relationship with the service user or their representative;
 - the skills and experience of the nominated point of contact; and
 - any specific requirements the service user or their representative may have, such as preferred method or language of communication, appropriate to their age, level of understanding and taking into account any specific conditions which may be relevant.
- how the notification process would work if the adverse outcome triggering the duty is brought to the attention of the NHS body by the patient or their family member/advocate.
- what to do if some information is not yet available or if the NHS provider needs information from the service user, or their representative, as part of their enquiries; and
- instances where there is a delay in notification.

Support for the service user at the notification stage

Some service users may find it distressing to learn an adverse outcome they have experienced may have been the result of treatment they received, and there will also be situations where some service users may have difficulty understanding the information provided in the notification.

This section of the guidance will seek to outline how a provider of NHS services can

ensure it is offering appropriate and proportionate support to service users as part of the notification process. This may include:

- when it may be appropriate for an NHS provider to offer support to a service user, even though in many cases it will not be required;
- practical examples of the nature and level of the support and remedial care that may be appropriate in different circumstances;
- how some service users may have difficulty understanding information provided in the notification;
- an explanation of how the duty links to the arrangements currently in operation as part of Putting Things Right; and
- sign posting to support services such as specialist advice and advocacy or arranging communication support or interpreters.

Communication with the notified individual post notification

Effective communication is about more than just exchanging information. This section of the guidance would seek to provide guidance for NHS bodies on how they should maintain communication with service users, or their families, post notification to ensure messages are clear, avoiding, wherever possible, frustration and conflicts. It could include details on:

- engaging with the service user, or their representative, to discuss the content of the notification;
- understanding and managing expectations around the further enquiries or reviews the NHS provider should undertake and communicating realistic timescales;
- ensuring that appropriate support, where needed, has been put in place
- making arrangements for ongoing communication including involvement in any subsequent inquiry/review;
- communicating the outcomes or results of any further inquiries /reviews;
- how to handle requests for further information from the service user, or their representative;
- where the service user, or their representative, contacts someone other than the 'nominated individual';
- how to conduct communications where more than one NHS provider is involved in the inquiries;
- signposting to the Putting Things Right arrangements and advocacy support;
- what to do if the service user, or their representative, decides to take legal action following notification; and
- the requirement to keep records.

Enquiries/ reviews

All cases in which there is an adverse outcome that triggers the duty will require some level of inquiry or review to be undertaken, in order for the body to understand and explain what has happened and why. In line with Putting Things Right principles, an enquiry/investigation that is proportionate to the harm caused will need to be conducted.

This section would make links to the Putting Things Right guidance which includes serious incident reporting requirements, and would clarify the steps to be taken by a NHS provider under the duty when either inquiries or an investigation is required as a result of an adverse outcome experienced by a service user. The Putting Things Right regulations will be amended to ensure the duty of candour procedure is embedded within its process.

This section would also outline the intent behind the duty; namely that investigations should not be used to highlight individual failures or apportion blame, but to enable learning and improvement. It would provide guidance in support of investigations being conducted in keeping with this intent, including how they can be used as tools to support organisational reflection and learning and to help ensure openness and honesty is a normal part of organisational culture across the NHS in Wales.

It would also provide guidance on how bodies can document investigations to collate the types of evidence required to demonstrate compliance with the duty while ensuring a supportive environment whereby all staff in NHS Wales are actively encouraged to be open and honest and feel safe and supported when indicating the duty should be triggered.

Reporting

This section would highlight how being open and honest:

- provides opportunities for both the reporting body and other providers to learn from what happened;
- contributes to generating the cumulative data and evidence required to drive improvement; and
- encourages decisions about services to be based on what matters most – the outcome for current and future service users and their families.

Requiring bodies to report on an annual basis will encourage individuals and organisations to reflect and learn; promoting a culture of openness and transparency in the system, which will in turn promote patient trust in the health service; and provide an annual baseline to help identify where services need support to improve with a view to avoiding future incidents.

This section would provide guidance for NHS bodies on the reporting requirements under the duty as set out within the Act. This would include further details on:

- whom the duty to report falls upon, including in circumstances where more than one NHS body was involved in the provision of the care and treatment;
- when to produce the report i.e. as soon as practicable after the end of each financial year;
- the content of the report including, as required within the Bill, how many times the duty has been triggered, a brief description of the circumstances in which the duty came into effect, and any steps taken by the provider with a view of preventing similar circumstances arising in the future;
- the requirement for primary care providers to prepare a report and supply this to any Local Health Boards they have arrangements with to provide NHS care;
- collation and incorporation of primary care providers' annual reports within those produced by a Local Health Board;
- alignment with the annual Putting Things Right Report; and
- the requirements for publication of the report and to make it easily accessible.

This section may also set out the processes for record keeping, including that all incidents triggering the duty should be recorded on local incident management systems in line with their local policies, and are coded as triggering the duty.

This section may also set out:

- how Local Health Boards and NHS Trusts should use the data gathered, through reporting annually on candour, to help inform the new annual quality reports; and
- how providers of NHS care can evidence they are promoting a culture that encourages candour and learning that stems from it.

Separately, this section would set out that the expectation that NHS providers should include, within local commissioning arrangements, the need for data on candour from the provider.

Staff support and training

When something has gone wrong, the feelings of staff should not be forgotten as although an investigation will be carried out sensitively, staff may feel they are at fault and consequently be less ready to ask for assistance if they are feeling under pressure or distressed. Whilst some investigations can be handled quickly, some can take months. In these circumstances, an organisation must be aware of the impact this may have on the wellbeing of their employees.

This section would outline our expectations of NHS providers in relation to providing support for staff on an ongoing basis; providing an overview of what providers should consider when developing local policies for managers of staff involved in traumatic/stressful events and the staff themselves. It would reinforce how the health and wellbeing of the NHS workforce is paramount to delivering effective patient care and fulfilling the visions set out in A Healthier Wales and in particular the Quadruple Aim. For example this could include signposting:

- the intended training, additional materials and supporting documentation which would be publicly available (details of these are contained within the Regulatory Impact Assessment supporting the Bill at paragraphs 261-279);
- well-being support for staff who may have been involved in incidents that result in harm; and
- how NHS providers can work collaboratively with Trade Unions to ensure that staff feel confident to raise concerns freely.

Technical section

This section would explain what is meant by the term “NHS body” in the Bill i.e. which bodies are subject to the duty of candour. It would also explain which organisation is responsible for complying with the duty in situations where one body provides services on behalf of another body.

It would also explain that the Welsh duty of candour applies in relation to treatment provided by NHS providers in Wales. However, if a Health Board makes arrangements for a Welsh resident to receive NHS care in England, it is the English duty of candour that would apply.

It would also make clear that the triggering of the duty does not mean the treatment provided was negligent. Section 2 of the Compensation Act 2006 which applies in relation to England and Wales provides that an apology, offer of treatment or other redress shall

not of itself amount to an admission of negligence or breach of statutory duty.

FAQs

This section would set out a series of anticipated common questions, supported by answers. It could also reference any training or additional information for further learning.

This section could use case studies to help contextualise and reinforce any learning points.

How the duty of candour operates in other UK countries

The duty of candour in the Bill seeks to provide an overarching framework which will be underpinned by regulations and guidance. It is purposely prescribed in this way as we have learnt from the duties already in place in England and Scotland i.e. in Scotland a large amount of detail is contained within primary legislation, making it unduly inflexible.

A table showing the different legislative approaches taken in England, Scotland and the Bill:

	England	Scotland	Bill
Powers	Primary legislation Health and Social Care Act 2008	Primary legislation Part 2 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016	Primary legislation
Trigger	Regulations Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20	Regulations Duty of Candour Procedure (Scotland) Regulations 2018	Regulations and statutory guidance developed with the assistance of clinicians and service users.
Procedure			
Notification			
Threshold			

English duty of candour:

The regulatory system in England is significantly different compared to Wales. In England, the duty of candour is imposed in regulations that apply to all services registered by the Care Quality Commission (“CQC”). Under the Health and Social Care Act 2008 (“HSCA 2008”), all providers of “regulated activities” must be registered with the CQC and must comply with the requirements of registration. “Regulated activities” are activities that relate to the provision of health and adult social care and that are set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (SI 2014/2936).

The CQC monitors compliance with registration requirements. This registration includes the nomination of a ‘Registered Person’ who is ultimately accountable –this would usually be the Chief Executive or another senior officer.

The English duty of candour is applied only to this Registered Person. However the guidance supporting this duty explains that: *“the approach taken hopes to encourage a culture of openness and transparency within health and social care services, at all levels within organisations”*.

Whilst this approach to the duty is different to what is proposed in the Bill, it intends to achieve the same effect – an organisation-wide duty of candour. The difference in approach is simply due to the fact that in Wales we do not register NHS bodies or require the nomination of a registered person.

Scottish duty of candour:

In Scotland a duty of candour was provided for in Part 2 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 (the Scottish Act). The duty came into force on 1 April 2018.

The duty itself is placed on the face of the Scottish Act in section 21. Section 21 describes incidents which give rise to the duty of candour procedure. The Scottish duty of candour applies to a 'registered person', which is defined within Section 25 of the Scottish Act as including a health board or someone entering into a contract with a health board to provide health services (i.e. primary care providers). This is consistent with the approach taken in Bill as it places the duty at an organisational level.

Social care duty of candour:

In Wales, the duty of candour in social care is set out within regulations made under sections 27 and 28 of the Regulation and Inspection of Social Care (Wales) Act 2016 (the Act). For example, within the Regulated Services (Service Providers and Responsible Individuals) (Wales) Regulations 2017 ("the 2017 Regulations"), Regulation 13 requires providers of regulated services to act in an open and transparent way with individuals (service users) and their representatives. Regulation 83 places the same duty on a service provider's designated 'Responsible Individual' who in respect of a body corporate, under section 21(2) of the Act, must be a 'director or similar officer' of the body.

This regulatory duty is supported by statutory guidance which further clarifies expectations, including that service providers have policies and procedures in place to support a culture of openness and transparency, and ensure that all staff are aware of and follow them. These requirements and expectations underpin inspections undertaken by Care Inspectorate Wales. This approach seeks to embed a service-wide culture of honesty and openness – not just when things go wrong.

In addition there are a number of other requirements in the 2017 Regulations which support the duty, such:

- having systems in place to record incidents (and complaints);
- the keeping of records and a requirement to document events that would be classed as harm events; and
- that continuous improvement is demonstrated via quality of care reviews, undertaken at least every six months.

During the Health, Social Care and Sport Committee evidence session on 11 July, it was suggested that the duty of candour in social care is more specific than the duty proposed within the Bill. The approach taken in social care is broadly aligned with the Bill's candour provisions, in that it provides organisational requirements placed on the service provider and/or responsible individual - demonstrating that service providers have a culture of

improvement through continuous analysis of incidents, notifiable incidents, safeguarding matters, whistleblowing, concerns and complaints.

Cross border care:

In terms of cross border care, we have considered the application of the duty of candour within the Bill on Welsh patients who receive healthcare in England and vice versa.

Where a Welsh resident receives care from a service in England the duty of candour in England will apply rather than the Welsh duty. This arrangement will be reciprocal for English residents accessing NHS services in Wales.

The system has to operate in this way or we would have providers being subject to both the English and Welsh duties when a patient from one country receives treatment in the other, generating unnecessary duplication.

Duty of Candour Bill provision

The duty within the Bill is placed on NHS bodies and primary care providers at an organisational level and not placed on individual health care staff. However, in practice, in order to ensure the legal duty is being discharged organisations must ensure that all staff, including managers, clinicians and administrators, act in a way which complies with the duty. All organisations will need to have a comprehensive policy in place setting out how it will operate and comply with the duty and how it will expect and support its staff to do so.

An organisational duty will ensure that it is a priority, at every level within an organisation, to help achieve the behavioural change necessary to successfully implement the duty. This will support an environment, not only where professionals are acting in an open and honest manner but where organisations are actively encouraging and are receptive of this behaviour.

Whilst professional ethics and obligations are crucial, they are insufficient by themselves to ensure a culture of candour throughout an organisation and, in any case, not all staff are covered by such professional duties. Placing the duty at an organisational level helps create the conditions for all staff – clinical and administrative – both to act and be supported to act in an open and candid manner.

As set out above the approaches taken in England and Scotland to the duty of candour, and that taken in social care in Wales, align to the intent of the Bill in that they all seek to achieve an organisational approach to candour.

Furthermore, enabling the Welsh Ministers to set out the candour procedure in regulations maintains sufficient flexibility to ensure the procedure is workable and can respond to any potential need to adapt, as a result of feedback and learning from both the NHS and service users, without the need to amend primary legislation. For example, the detail may need to be amended in response to changes in models of care and working practices, to learn from the experiences of service users and to take into consideration how the procedure operates in more complex cases.

The threshold of harm that needs to be met before the duty of candour will be triggered is set within Section 3(4) of the Bill, as harm which is ‘more than minimal’. However, it is considered that in order to define this in a way that is comprehensive, is straightforward to apply to different types of care and is presented in a way that is understood by both clinicians and users of services the description of this will be covered in statutory

guidance, provided for in Section 10 of the Bill. A working group will be established to develop the guidance, which will include clinicians, other professionals concerned and lay representatives. This will help ensure it is clear to both providers and service users what level of harm must occur before the duty of candour is triggered.

Both England and Scotland have produced guidance to support their duty of candour legislation. Compared to England, Scotland took a much more prescriptive approach which included the inclusion of case studies. We have learnt from this inclusion of practical examples and will use it as a model to frame the planned guidance in Wales so that our expectations in different circumstances are clearly understood.

A draft outline of this planned statutory guidance to support the duty of candour has been produced and is enclosed at **Annex 3**.

Change in approach to appointing board members

Current position with Community Health Councils (CHCs)

CHC Board Members

The national CHC Board is comprised of 12 members:

- the chair and two independent members are appointed by the Welsh Ministers through the public appointments process;
- seven members are the persons elected as chair of each of the seven regional CHCs⁵; and
- two CHC staff members, who are employed by Powys Teaching Health Board. These are the chief executive of the Board of CHCs and a CHC staff member who is appointed by fellow CHC staff members.

Volunteer members

Under the current CHC arrangements, the Welsh Ministers appoint 50% of volunteer members through the public appointments process, 25% are appointed by local authorities and 25% by voluntary organisations. They are appointed for a term of up to four years and may serve a maximum of two terms. In addition, CHCs may appoint co-opted members (who do not have voting rights) for a maximum period of two years.

It is becoming increasingly difficult to attract volunteer members. We know from having spoken to applicants and from discussions with the CHCs that many people find the public appointments process, which requires a formal application process and panel interview, off-putting and many able would-be candidates are deterred from applying.

In recent years we have struggled to recruit sufficient members to fill Welsh Minister-appointed vacancies on CHCs. In 2017/18 we appointed 43 members which was insufficient to fill the 55 vacancies across Wales. In our 2019 recruitment we only had 8 applicants for 34 vacancies which meant we had to extend the application period for a further four weeks. The extension only yielded a further 13 applicants.

The low number of applicants persists despite investment on funding adverts in both the print media and online and concerted efforts by both the CHCs and Welsh Government to publicise the vacancies and encourage applications.

Bill proposals

Board of Citizen Voice Body

The Bill proposes that the Welsh Ministers appoint the Board of the Citizen Voice Body. Concerns were raised at Committee and in Plenary that this approach may compromise the independence of the new Body. However, the precedent for Ministerial appointment to

⁵ In accordance with regulation 15 of the Community Health Councils (Constitution, Membership and Procedures) (Wales) Regulations 2010, the members of a CHC must elect one of their number to act as chair for a period of up to three years.

Welsh Government Sponsored Bodies is well established with, for example, the Welsh Ministers appointing the Boards of Social Care Wales, Qualifications Wales and the Higher Education Funding Council for Wales.

In addition, all appointments will be governed by the Governance Code on Public Appointments which requires all Ministerial appointments to public bodies to be the subject of open and fair competition, with appointment based on merit. The ultimate responsibility for appointments to the Body rests with the Welsh Ministers who are accountable to the National Assembly for Wales.

Paragraph 2 of Schedule 1 to the Bill governs appointments and provides that the Board shall be comprised of a Chair, a Deputy Chair and at least 7 but no more than 9 members in total.

Volunteer members of the Citizen Voice Body

As an independent body corporate, the new Body will have the power to appoint its own volunteer members. The members appointed by the Body will not be subject to the public appointments process, nor will there be imposed limits on the amount of time a person can serve as a member. Therefore, with the new Body we are removing some of the current actual and perceived barriers to membership. This has been welcomed by the current CHCs.

We have already spoken to the Wales Council for Voluntary Action and they have agreed to give us the benefit of their experience and lend us their help and support in developing a volunteering model for the new Body that is sustainable, [builds on existing networks] and helps to attract volunteers that are representative of the users of health and social services.

We have also spoken to the Patient and Client Council in Northern Ireland, a body that exercises similar functions as to those intended for the Citizen Voice Body. They have established a successful membership model that may provide a useful precedent. Their model operates on a number of levels with a large online membership who support calls for evidence, complete consultations, surveys etc. and members who are physically present and active in the work of the Body.

An active, committed and representative volunteer member base is essential to support the work of the new Body and, as set out above, consideration is already being given to how, when we are establishing the Body, we can ensure, from the outset, the membership model is fit for purpose.

As set out at paragraph 505 of the Explanatory Memorandum, in order to support the establishment of the new Body the intention is to set up an Implementation Board. One of the workstreams will be tasked with consideration of the volunteer membership model and will be comprised of representatives from the current CHCs, the WCVA, when appointed, the senior team of the new Body and other key stakeholders, including Welsh Government. As well as recruitment of members, this group will also look at matters such as training needs of volunteers.

Expectations for the Operation of the Citizen Voice Body

The Citizen Voice Body (“the Body”) needs to play a vital role in ensuring the citizen voice is represented in all matters related to health and social services at a national, regional and local level.

The Body will need to engage with and develop constructive relationships with partners in Wales. That includes members of the public, health boards, trusts, special health authorities, local authorities, Regional Partnership Boards, Public Service Boards, the inspectorates, statutory commissioners, Social Care Wales, the third sector and others to ensure the voice of the citizen is represented and heard.

It will be especially important for the Body to develop strong relationships with its partners so they can share knowledge and learning of the outcomes that emerge from the views they obtain from people.

The Body will need to work with, rather than replace, fora that already exist for representing the views of citizens in matters related to health and social care, such as Citizen Panels established under the Regional Partnership Boards.

A key part of the Body’s role will be to gather and represent the views of citizens with a view to providing those with responsibility for the provision of health and social care with information on the views and experience of service users to help drive improvement and achieve better outcomes.

Legal Framework

- It will be established as a Body corporate, able to employ staff and enter into contracts and leases.
- Its functions are set out on the face of the Bill.
- The Board is appointed by the Welsh Ministers through the public appointments process.
- The chief executive has accounting officer status. Welsh Ministers will specify the accounting officer’s responsibilities in relation to the Body’s accounts and finances.
- The Auditor General for Wales will supply the external audit function.
- The Body has the power to appoint its own volunteer members, outside the public appointments process.

Remit Letter

- Like all Welsh Government Sponsored Public Bodies, the Body will have a remit letter.
- The remit letter will set out the funding the Body is to receive from Welsh Government.
- The letter will also set out the “key deliverables” for the Body in terms of, for example, delivering its functions across health and social care services, providing services to the population of Wales on a local and national basis; being an

organisation that is ambitious and learning and supports a culture of learning and improvement amongst staff and members etc.

- Given the nature of the functions the Body will exercise and due to the requirement in paragraph 19 of Schedule 1 to the Bill for the Body to set its objectives and priorities for the year following consultation, the remit letter will respect the need for the Body to be operationally independent, for example, having freedom to determine for itself areas for thematic reviews and engagement etc.

Annual Plan and Annual Report

- Paragraph 19 of Schedule 1 to the Bill requires the Body to produce an annual plan setting out how it proposes to exercise its functions during the coming year.
- The expectation is that the Body will give equal weight to the exercise of its functions across both health and social services.
- The plan must include a statement of the Body's objectives and priorities for the year.
- The Body is under a duty to consult with such persons it considers appropriate on its proposed objectives and priorities.
- Paragraph 20 of Schedule 1 requires the Body to produce an annual report setting out how it has exercised its functions during the year. A copy of the report must be given to the Welsh Ministers and a copy laid before the National Assembly for Wales so the actions of the Body are open to scrutiny.

Implementation Board

- The target date for establishing the new Body is 1 October 2021.
- There will not be any time lapse between the abolition of the CHCs and the establishment of the new Body. The clear expectation is for CHCs and health bodies to operate on a "business as usual basis" until the new Body is established.
- To facilitate the establishment of the new Body, an Implementation Board will be established. The core group will be comprised of representatives from Welsh Government, Powys Teaching University Health Board (as employer of CHC staff), representatives from the current CHC and, when appointed, the Board and chief executive of the new Body.
- Individual work streams will be established to consider matters such as transfer of staff, accommodation, IT procurement, volunteer membership, governance etc.
- The core group will be supplemented with people with expertise in the areas covered by the individual work streams.

Location/accommodation

- The Bill does not prescribe a structure for the Body.
- We want the Body to have the ability to determine where it needs offices, based on its own assessment of need.
- The expectation is that the Body will be organised in such a way as to enable it to perform its functions at a local as well as a national level.

- The regulatory impact assessment bases the Body's accommodation needs and costs on current CHC accommodation location and costs: 12 offices of varying sizes across Wales.
- Current thinking, and this will be the subject of discussion at the Implementation Board, is that the new Body needs a different accommodation strategy to the CHCs. CHC offices are often based on industrial parks which are not particularly accessible to the population who wish to use their services. Going forward there is merit in exploring smaller town centre premises for the Body's offices and/or co-locating the Body's offices with other providers of public services such as community hubs or libraries. This will make the Body more accessible to the public.

Relationship with partners

- The Body will need to establish itself as a key partner in the health and social care fields. It will need to agree with partners such as the inspectorates, health boards, local authorities, the voluntary sector, Regional Partnership Boards, Social Care Wales, the Commissioners etc how it will work with them.
- This is something that Welsh Government can help to facilitate as part of the Implementation Board arrangements: assisting the Body to make connections with partners.
- High level discussions have already been held with the inspectorates (HIW and CIW) who are supportive of the potential for partnership working agreements between themselves and the new Body. The partnership agreements would cover matters such as information sharing and escalation of concerns.
- The expectation is for NHS bodies and local authorities to have clear arrangements in place for making use of the information provided to them by the Body. NHS bodies would, for example, need to have clear systems in place to ensure any feedback on patient experience/quality of services received from the Body was reported to and considered by their Quality and Safety Committees.
- The Welsh Government, drawing on the experience of those involved in the Implementation Board, can also produce guidance on how Health Boards, Trusts, Special Health Authorities and Local Authorities can fulfil their duty under section 17 of the Bill to promote the activities of the Body.
- There are some legislative changes that Welsh Ministers propose to make to help frame the relationship between the Body and existing partners who work in the areas of health and social care as a positive one of partnership and co-operation:
 - The Body will have the status of "other partner" on Public Service Boards (PSBs) established under the Well-being of Future Generations (Wales) Act 2015. 'Other partners are individuals or bodies considered to be important providers and representatives of public services. A PSB must seek the advice of their other partners and involve them in the activities of the PSB in the manner, and to the extent, that the board considers appropriate. This may include seeking their partners' advice on, or involving them in, the preparation, implementation and delivery of local well-being plans. The Body will therefore be able to comment on PSBs action plans from both a health and social services perspective, adding a greater integrated focus.

- Regional Partnership Boards (RPBs) are established under the Social Services and Well-being (Wales) Act 2014 to oversee the partnership arrangements put in place between health boards and local authorities for the delivery of integrated and sustainable care and support services. 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 bodies under partnership arrangements to consult with the Citizen Voice Body in the preparation of these assessments and plans. The Body will therefore 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. To do this, the Body will also need to make linkages with the Citizen Panels that support the work of the RPBs.

Complaints advice and assistance

- The Body will be able to provide complaints advice and assistance to a broader range of people than the current CHCs.
- Stakeholders with whom we have discussed the Bill, have indicated it would be useful if there was guidance to set out:
 - which complaints the Body is able to assist with;
 - which it cannot;
 - circumstances when the Body may need to co-operate with other providers of advice and assistance; and
 - arrangements for signposting people to other options for advice and support.

The expectation will be that the Body will provide information to inform the public, seeking views from the voluntary sector.

Membership

- As a Body corporate, the Body is able to recruit its own volunteer membership, outside the public appointments process.
- It is important to have the membership model up and running from the outset as the Body will need the support of its volunteers to perform its functions.
- Consequently, it is intended that the Implementation Board will assist in the development of the model.
- Officials have approached the Wales Council for Voluntary Action who have agreed to lend their support in the development of a model that is sustainable and aims to attract volunteers who are representative of users of health and social services.

Representations

- The Body has the power to make representations to a Health Board, Trust, Special Health Authority or Local Authority about any matter connected with the provision of a health service or social services.
- Those bodies are placed under a legal duty to “have regard” to the representations. The legal duty to have regard to representations and the development of appropriate mechanisms for taking the substance of the representations into account will ensure the voice of the citizen is built into the decision making process and heard by and listened to by decision makers
- This means that the representations **must** be taken into account by these bodies when they are exercising functions relevant to the representations.
- The expectation is that NHS bodies and local authorities will consider how each representation is best taken into account. This may involve sharing representations with Quality and Safety Committees, or scrutiny committees or sharing relevant representations with partners such as RPBs and PSBs so that the voice of service users is truly embedded and taken into account in the decision making process. Representations may, for example, relate to service changes proposed by NHS bodies or local authorities and may also be taken account in relation to the planning process, they could also take the form of thematic reviews of services.
- The expectation is that the Body will not make representations about matters relating to identifiable individuals. Concerns about care or treatment of individuals should be made through the relevant complaints procedure.
- The new duty of quality in the Bill places a duty on NHS bodies to exercise their functions with a view to securing improvement in the quality of health services. Quality includes, but is not limited to, quality in terms of the experience of individuals to whom health services are provided. There are clear linkages between the way NHS bodies can demonstrate quality improvement and consideration of representations from the Body.
- The expectation is that the Body will engage with and develop constructive relationships with NHS bodies and local authorities and having regard to representations will form part of the on-going and continuous engagement with these bodies. CHCs have called for NHS Bodies and local authorities to be required to formally respond to representations made by the Body. Officials have met and are engaging with the Board of Community Health Councils in Wales to further discuss this.

Visiting

The clear expectation is that the Body will be able to access service users at the point of delivery of care for the purposes of seeking their views about matters related to health and social services. This is one of many ways that the new Body will be able to seek the views of the public.

Officials have had constructive discussions with the Board of Community Health Councils in Wales over the summer to explore how the CHCs currently use their power of entry and to discuss how we might enable access to health and social care premises for the Body. These discussions are ongoing.