

Y Gymdeithas Feddygol Brydeinig  
Pumed Llawr  
2 Pentir Caspian  
Ffordd Caspian  
Bae Caerdydd  
Caerdydd  
CF10 4DQ

British Medical Association  
Fifth Floor  
2 Caspian Point  
Caspian Way  
Cardiff Bay  
Cardiff  
CF10 4DQ

# BMA

Cymru Wales

## Population Healthcare Division

Health and Social Care Group  
Welsh Government Offices  
Cathays Park  
Cardiff

CF10 3NQ

[HSCQualityandEngagement@gov.wales](mailto:HSCQualityandEngagement@gov.wales)

13 December 2022

## Consultation on the Statutory Guidance and Regulations required to implement the Duty of Candour

### BMA Cymru Wales Response

#### INTRODUCTION

The BMA is a professional association and trade union representing and negotiating on behalf of all doctors and medical students in the UK. It is a leading voice advocating for outstanding health care and a healthy population. It is an association providing members with excellent individual services and support throughout their lives.

BMA Cymru Wales generally supports the introduction of an organisational-level Duty of Candour, which we feel could support the need to engender a culture in which the raising of concerns is encouraged. Implemented appropriately, we feel it could play an important role in helping to create an NHS with an operational culture that is not rooted in blame but supports and encourages learning and improvement.

We previously responded to the consultation on the Health and Social Care (Quality and Engagement) (Wales) Bill, broadly welcoming the aspirations of the Bill to embed a culture of openness, transparency and candour in the Welsh health and care sectors. Our response called for mitigations to the potentially burdensome impact of the Bill, particularly in primary care, as well as further guidance to enable healthcare workers to define the point at which the Duty is triggered. We reiterated these concerns at Duty of

#### Cyfarwyddwr Cenedlaethol (Cymru)/National director (Wales):

Rachel Podolak

Cofrestrwyd yn Gwmni Cyfyngedig trwy Warant. Rhif Cofrestredig: 8848 Lloegr  
Swyddfa gofrestrdig: BMA House, Tavistock Square, Llundain, WC1H 9JP.  
Rhestrwyd yn Undeb Llafur o dan Ddeddf Undebau Llafur a Chysylltiadau Llafur 1974.  
Registered as a Company limited by Guarantee. Registered No. 8848 England.  
Registered office: BMA House, Tavistock Square, London, WC1H 9JP.  
Listed as a Trade Union under the Trade Union and Labour Relations Act 1974.



Candour stakeholder engagement events held by Welsh Government in late 2021 and early 2022.

Despite raising these issues, alongside other concerns, BMA Cymru Wales is not wholly satisfied that they have been sufficiently addressed in the guidance provided and feel that the system as proposed is fundamentally flawed. Given this, we don't feel able to provide a full response to the extensive number of questions posed. Before this can be done, much more clarity is needed on when the Duty may apply, as we seek to explain further.

### **WHEN THE DUTY OF CANDOUR APPLIES**

As stated, we do not believe that the guidance is sufficiently clear on when the Duty of Candour applies. The equivalent organisational duty in England has a perhaps more clear-cut trigger point, taken effect upon the occurrence of a “*notifiable safety incident*”<sup>1</sup>

The proposed Welsh Duty is triggered when two conditions are met. The first condition is that the service user ‘to whom health care is being or has been provided by the body has suffered an adverse outcome’.

It goes on to say that a service user is to be ‘treated as having suffered an adverse outcome if the user experiences, or if the circumstances are such that the user could experience, any unexpected or unintended harm that is more than minimal’.

This definition presents a number of challenges. Whether a harm is, or could be in future, ‘more than minimal’ requires a clear judgement to be made and this can often be entirely dependent on a whole range of different circumstances.

For example, the level of harm framework (Annex B) suggests a potential scenario of ‘minimal’ unintended harm is an increase in a hospital stay by up to three days. But this is dependent on several factors, not least a patient’s total length of stay or any personal circumstances that may exacerbate the harm.

Furthermore, the concept of applying this unclear threshold to an adverse outcome that has not yet arisen, and may not in fact arise at all, is similarly challenging.

In many cases, whether an incident meets this first condition will be a wholly subjective determination based on different circumstances in each case. Given the scope of potential scenarios that could play out in a wide range of different healthcare settings (and between such settings), we remain unconvinced that the guidance will lead to the Duty of Candour being applied clearly and consistently across Wales.

---

<sup>1</sup> The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:  
<https://www.legislation.gov.uk/ukdsi/2014/978011117613/regulation/20>

The second condition is that the ‘provision of the health care was or may have been a factor in the service user suffering that outcome’. This presents further challenges, such as how to determine whether the provision, or lack of provision, of health care was a factor, or may have been a factor, in the adverse outcome.

## SYSTEM PRESSURES

We also have concerns about how the conditions needed to trigger the Duty will apply to those waiting for diagnostics or treatment who suffer an adverse outcome. The statutory guidance provides an example on p27:

*a Service User is on a waiting list for a heart bypass, and they have a heart attack while on the waiting list this isn't unexpected and is a risk that has been explained to the patient as to why they need surgery and so the Duty wouldn't apply.*

Whether the heart attack was expected or otherwise would be down to clinical judgement. However, this fails to account for the length of time the service user is waiting and whether this is in line with best practice or is otherwise reasonable. Whether a patient is waiting days, weeks, months or years for a treatment is surely material factor in determining whether this condition is met.

Of course, linked to the length of time people may wait for care, is the shortages of staff across various specialities, coupled with increased demand due to pandemic related backlogs, winter pressures and other long-established workforce issues.

Given the serious systemic issues in the health service, we have serious concerns that under the proposed regime, most current patient interactions with the NHS would trigger the Duty of Candour. Recent hospital treatment waiting times data reveals there are a record 754,677 patient pathways awaiting treatment. Additionally, people are waiting longer in Wales when compared to other nations, with 24% of waits for treatment in Wales being over a year: a time period where deterioration of a condition could feasibly occur<sup>2</sup>. This could lead to a situation where doctors and other healthcare professionals are forced to apologise to patients who suffer adverse outcomes because of pressures in the system which are no fault of their own, and who have themselves been highlighting these pressures and the impact that they will have on patients' experiences<sup>3,4</sup>.

With this likelihood in mind, we have similar fundamental concerns about how the Duty as proposed would work in the interface between primary and secondary care, when each are considered to be two separate organisations within the regulations, with their own policies and procedures in place.

<sup>2</sup> BBC News (2022) NHS Wales: Ambulance handover delays treble in two years: <https://www.bbc.co.uk/news/uk-wales-63642328>

<sup>3</sup>BMA (2021) Why Wales needs safe staffing for all by Dr David Bailey, Chair British Medical Association's Welsh Council: <https://www.bma.org.uk/bma-media-centre/why-wales-needs-safe-staffing-for-all-by-dr-david-bailey-chair-british-medical-association-s-welsh-council>

<sup>4</sup> BBC News (2022) NHS Wales in dangerous and precarious state - BMA Cymru: <https://www.bbc.co.uk/news/uk-wales-63067230>

The guidance says:

*It is a bit more complex if a person is assessed by body A, then referred to body B who puts them on a waiting list. This is often the case with referrals between general practice and hospital care.*

We agree that this presents complexity given the way the guidance has been drafted, however, this is a typical and common occurrence experienced by huge numbers of people accessing the NHS every day. Data suggests that 73,922 referrals from a GP for secondary care treatment were made in September 2022 alone, and on average over 70,000 referrals were made per month during thus far 2022<sup>5</sup>. The guidance does not provide sufficient explanation as to how this complexity should be resolved, nor does it recognise the volume of occasions when such referrals are made.

The mechanisms by which an adverse outcome would be managed are far from clear, beyond a further vague example in Annex H, and there is no guidance as to what would happen in instances where both organisations can't agree on whether the Duty is triggered, who should notify and issue the apology, and where any administrative burden should fall.

We fear that this type of uncertainty could become the norm given the systemic pressures across the system. Patients in Wales should expect better of their health and care system and with that in mind we can see the clear merits for bringing forward such a duty soon. However, we are increasingly convinced that doing so in its current format will place heavy administrative burdens upon an already stretched workforce. Currently, this would only serve to further impair the functioning of health and care organisations.

## IMPACT ON GENERAL PRACTICE

Further to the above, we have additional concerns about the role and responsibilities of individual GP practices in Wales under the proposed guidance.

As has been much publicised, there are long-term difficulties with recruitment and retention into Welsh general practice and we should therefore be wary of introducing policies, procedures and regulations that would increase the pressure on already hard-pressed GPs and have negative impact on the fragility of the service. Due to the immense workload pressures faced by our members we have regularly advocated for the reduction in bureaucracy in general practice, and have made significant strides toward achieving this in successive GMS contract agreements<sup>6</sup>. However, the proposal

---

<sup>5</sup> Stats Wales (2022) Referrals by local health board (area of residence) and month: <https://statswales.gov.wales/Catalogue/Health-and-Social-Care/NHS-Hospital-Activity/Referrals/referrals-by-area-month>

<sup>6</sup> BMA (2022) Welsh GP contract 2022-23: <https://www.bma.org.uk/pay-and-contracts/contracts/gp-contract/welsh-gp-contract-2022-23>

as it runs contrary to this direction of travel and places additional administrative work upon each of Wales' 370+ GP practices.

We note the strength of the duties on primary care providers in the Health and Social Care (Quality and Engagement) (Wales) Act 2020. However, it's vital to ensure that guidance supports a clear and proportional implementation of the Duty of Candour. The guidance as drafted does not do this, and in treating individual contractor practices in much the same way as Local Health Boards with thousands of employees, fails to recognise the substantial and enduring pressures in primary care.

For example, the Health and Social Care (Quality and Engagement) (Wales) Act 2020 says a report under Section 5 must be provided to the health board 'as soon as practicable after the end of each financial year'. However, the guidance states that 'such reports must be provided to the relevant Local Health board by no later than 30th September each year'. Whilst we acknowledge the Duty provided for in the Act, the guidance seeks to arbitrarily set a more precise deadline on primary care providers without due recognition of workload pressures and competing priorities.

Many GP partners are already rethinking their career journeys due to the complexity of managing practices and we are seeing LHB managed practices increasing as a result. Whilst LHBs can share the administrative burdens associated with implementing the Duty across any number of staff, there will often only be a handful of staff working in general practice who will have to deliver on these duties on top of already excessive demand.

## RELATIONSHIP WITH PROFESSIONAL DUTIES

Doctors and other registered professionals are already subject to a Duty of Candour. Health professionals must be open and honest with patients when things go wrong, as set out in the *joint statement from the Chief Executives of statutory regulators of healthcare professionals: Openness and honesty - the professional duty of candour*<sup>7</sup>

Doctors are familiar with their long-standing obligations under the individual Duty of Candour. The new statutory Duty places additional responsibilities on medical staff, particularly general practice contractors, and this therefore needs to be mitigated.

There is a significant onus within the guidance on individual staff to report an incident, or near miss, and to carry out the appropriate follow up procedures. Clearly all staff have a role to play in implementing the statutory Duty, but it's important that organisations are able to dedicate resource to this and don't add further burdens onto existing professional duties.

---

<sup>7</sup> GMC (Accessed 2022), Joint statement from the Chief Executives of statutory regulators of health and care professionals: <https://www.gmc-uk.org/-/media/gmc-site-images/ethical-guidance/related-pdf-items/conflicts-of-interest/joint-statement-from-the-chief-executives-of-statutory-regulators-of-health-and-care-professionals.pdf?la=en&hash=A29836358B7C3AB3750A7CEAC6F49AEB5C76C1D>

The Welsh Government may also wish to consider the disparity between registered professionals, who are subject to both the professional and statutory duties, whilst senior NHS managers are only subject to the statutory Duty. This can mean that those with more responsibility for managing the working environment, including staffing levels, are not similarly burdened, despite having a significant influence on patient care and outcomes.

A further concern is how the statutory Duty will align with other responsibilities and organisational policies. We note that the guidance considers the link to the *Putting Things Right* policy, however, other policies may also factor depending on the nature of the incident in question and the circumstances surrounding it.

For example, an employee may raise concerns under the whistleblowing policy about a near miss or an adverse event, where they may have identified safety concerns or wrongdoing. Should such an incident then trigger the Duty of Candour, it would be helpful to have additional guidance on how this should be done in line with each of the relevant policies. It would not be reasonable, for example, for a health care worker who has identified such concerns to then have to make a notification and apology to a service user when no action has been taken to address the issues raised.

## **SUMMARY**

In summary, BMA Cymru Wales recognises and broadly welcomes efforts to develop a workable framework through which an organisational Duty of Candour can be clearly and consistently applied. Implemented appropriately, we feel the Duty could play an important role in helping to create an NHS with an operational culture that is not rooted in blame but supports and encourages learning and improvement.

However, at this stage we are not satisfied that the proposed regulations and statutory guidance allow for a clear and consistent determination of exactly when the Duty would be triggered, for the reasons outlined above.

These concerns are exacerbated given the current scale of system pressures. We are particularly concerned that, whilst the guidance recognises that referrals between primary and secondary care may present more complexity in relation to the Duty being triggered, it fails to present satisfactory solutions to how this complexity could be resolved.

This could further add to the already excessive responsibilities on General Practice where, for the purposes of this legislation, GPs have broadly comparable requirements placed upon them to those placed on entire health boards. This is a clear imbalance that could have a negative impact on an already fragile and highly pressured primary care system.

It is therefore disappointing that while we accept the potentially positive effects that the organisational Duty of Candour could have, the regulations and statutory guidance as written do not allow for these to be realised. We therefore cannot support the proposal in its current form.