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Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



Llywodraeth Cymru
Welsh Government

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Dai Lloyd AM
Chair
Health, Social Care and Sport Committee
National Assembly for Wales
Cardiff Bay
Cardiff
CF99 1NA

19 June 2019

Dear Dai,

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

Following the introduction of the Health and Social Care (Quality and Engagement) (Wales) Bill into the National Assembly for Wales on 17 June 2019, please find enclosed a copy of the statement of policy intent.

This document indicates my policy intentions for regulations that will set out the procedure to be followed when the duty of candour (provided for within section 4 of the Bill) is triggered. The document is provided to support the Committee's scrutiny of the Bill.

I look forward to providing evidence to the Committee in due course.

I am copying this letter to the Chair of the Constitutional and Legislative Affairs Committee.

Yours sincerely,

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

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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.



Llywodraeth Cymru
Welsh Government

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

Statement of Policy Intent for Subordinate
Legislation

June 2019

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1. Introduction

The statement of policy intent set out the current policy approach for the subordinate legislation for the Health and Social Care (Quality and Engagement) (Wales) Bill; “the Bill”. The proposal will be subject to its own consultation and scrutiny process and therefore may be subject to change. This document has been prepared in order to assist Committees during the scrutiny of the Bill and should be read in conjunction with the Explanatory Memorandum and Explanatory Notes.

The Welsh Government considers that these subordinate legislation powers are essential:

- in order to prescribe matters of procedural detail; and
- provide the flexibility for matters which may require adjustment to facilitate effective implementation and operation.

The key purpose of the Bill is to introduce changes that:

- impose a new duty relating to improvement in the quality of health services on NHS bodies and the Welsh Ministers in relation to their health service functions;
- reform and ultimately strengthen the arrangements for the voice of citizens across health and social care, further connecting people with the organisations that provide them with services;
- place a duty of candour on NHS providers in Wales, requiring them to be open and honest when things go wrong; and
- strengthen the governance arrangements for NHS Trusts.

For ease of reference, this document combines those provisions which are intended to be dealt with as part of the same statutory instrument, for example, within a set of regulations.

In developing subordinate legislation, the Welsh Government will work closely with stakeholders in order to ensure the provisions are relevant, valid and proportionate.

2. Regulations to provide for a ‘Candour Procedure’

REGULATIONS RELATING TO	A candour procedure
BILL PART	Part 3
SECTION	4(1) to 4(4)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>Part 3, Section 3 of the Bill sets out when the duty of candour applies.</p> <p>The duty applies to NHS bodies (which are defined in the Bill as Health Boards, Welsh NHS Trusts, Special Health Authorities (including NHS Blood and Transplant in relation to their Welsh functions) and primary care providers who provide care under arrangements with a Health Board.</p> <p>The duty is triggered when a service user to whom health care is being or has been provided by the NHS body suffers an adverse outcome. A service user is treated as having suffered an adverse outcome if the service user experiences, or if the circumstances are such that the service user could experience, any unintended or unexpected harm that is “more than minimal”.</p> <p>The meaning of more than minimal will be set out in guidance issued by the Welsh Ministers under section 10 of the Bill. The guidance will be developed with the aid of stakeholders, including clinicians, to ensure that it is practical and fit for purpose. An outline of the contents of the guidance and the nature of the workshops that will be established to develop the detail has also been prepared for the committees’ information.</p> <p>Part 3, Section 4 provides regulation-making powers which enable the Welsh Ministers to make provision about the procedure to be followed when the duty of candour is triggered.</p> <p>Section 4(1) requires Welsh Ministers to make regulations which specify a procedure which must be followed by NHS bodies in the event of the duty of candour being triggered.</p> <p>Section 4(2) sets out that regulations made under section 4(1) must require NHS bodies to give notification to the service user concerned, or someone acting on their behalf (“the service user”):</p> <ul style="list-style-type: none"> • that the duty has come into effect; • of the identity of a ‘nominated individual’ who will act as point of contact in respect of the candour procedure; and • any further enquiries carried out by an NHS body in respect of the circumstances in which the duty of candour came into effect. <p>Section 4(3) further requires the regulations to make provision:</p>	

- for an apology to be offered by the body;
- for the provision of support to the service user given notification described in subsection 2(a); and
- for the requirement to keep records.

Section 4(4) gives power to the Welsh Ministers to make any other provision in respect of the candour procedure which they consider appropriate.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulations made under Section 4 will provide a framework for how NHS bodies subject to the duty will be required to act in order to discharge the duty.

Section 4 is prescriptive about the fundamental elements that the duty of candour procedure must contain in order to ensure the detail set out in the regulations contains essential elements such as prompt notification, an apology, the detail of further enquiries carried out by the body into the circumstances that caused the adverse event etc. However, enabling the Welsh Ministers to set the procedure in regulations maintains sufficient flexibility to ensure the procedure is workable and can respond to any potential need to change the procedure as a result of feedback and learning from the NHS and service users without the need to amend primary legislation.

The regulations will establish a procedure and lead to behaviours that support the key principle underpinning the duty of requiring NHS bodies to act in a way which is upfront, open and transparent when an “incident” occurs. This will help achieve a position of consistent and routine practice whereby openness and transparency with service users in relation to their care and treatment, becomes a normal part of the culture across NHS bodies in Wales.

It will also build on the “Being Open” principles that are embedded in the Putting Things Right¹ process (the process for managing concerns, including complaints and serious incidents within NHS Wales). The duty of candour procedure will be a key component of the Putting Things Right arrangements and this will require some amendments to the existing regulations that underpin the Putting Things Right process: the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (“the PTR Regulations”) and the supporting guidance.

In particular, it is envisaged the PTR Regulations will be amended to ensure the duty of candour procedure is embedded in the Putting Things Right process and if the duty of candour procedure is triggered the requirements for a proportionate investigation set out in regulation 23 of the PTR Regulations will apply.

There will also be a need to make amendments to the existing PTR Regulations so that they comply with the requirements in section 4(2) of the Bill for the Welsh Ministers to make regulations that ensure a NHS body “on first becoming aware that

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>

the duty of candour has come into effect” to give notice to the service user or someone acting on the service user’s behalf.

Currently section 12(7) of the PTR Regulations applies when a member of staff has reported a concern about a patient’s treatment. Under section 12(7) the duty to notify a service user (or their representative) of the concern/incident only arises after the Body has conducted an initial investigation of the concern and where that investigation has demonstrated the patient has suffered moderate or severe harm or death.

The regulations made under section 4(2) of the Bill will move the act of notifying the service user forward to the point when the NHS body is first aware that the duty of candour has been triggered, rather than after the initial investigation has completed. This ensures all instances of harm will be disclosed to the service user who experienced the harm (or their representative) and supports lessons being learned to make the events which led to the incident being less likely to occur again in the same or a different setting.

Subject to consultation on the detail, it is intended the regulations will require the NHS body to make all reasonable efforts to contact the service user in order to comply with the duty to notify. The regulations will also deal with circumstances in which a service user is represented by another person. They will also require the NHS body to establish the service user’s preferred method of communication and, in the event the service user not wishing to receive any further communication in respect of the incident, to be respected by the body. This does not mean the investigation into the incident should stop (as there may be wider learning from the incident) but there will be no further involvement of the service user.

It is also intended that any notification requirements would require the body to provide the service user with an account of the incident that triggered the duty (based on the information that is available to the body at the time the duty is triggered). This would provide useful background to the information on any further enquiries the body intends to take into the circumstances of the incident that triggered the duty (which has to be part of the candour procedure by virtue of the requirements in section 4(2)(b)(ii) of the Bill).

Section 4(2)(b)(i) of the Bill provides the candour regulations must contain a provision which requires the NHS body to notify the service user or their representative of the identity of a person within the organisation who will be their point of contact should they have any questions as the candour procedure is followed. The identity of the person will vary depending on the nature of the incident in question. However, it is intended that the regulations will place a duty on NHS bodies to have regard to a number of matters including: (i) the nature and complexity of the incident and (ii) the severity of the incident when determining an appropriate point of contact. This will ensure that the nominated point of contact has the relevant

skills/experience to be able to answer any queries the service user may have. This encompasses the ethos of the 'Being Open' approach², where communication is open, honest and occurs as soon as possible following an incident.

The regulations will further support a change in the way NHS bodies communicate with service users when something has gone wrong with their care, building on the "Being Open" principles established under the Putting Things Right process. The candour procedure established under the regulations will:

- change the nature of the communication with the service user - ensuring they are informed as soon as the Body is aware that the duty has been triggered;
- that the service user is appropriately supported, informed, and assured the issues which led to the incident occurring will be addressed and lessons learnt; and
- encourage communication between NHS bodies and service users.

Evidence shows often what service users and their families or carers most want after an incident occurs, is an apology; a willingness to explain what went wrong; and an open approach to learning from mistakes³. Section 4(3)(a) of the Bill acknowledges the importance of an apology to service users and their families by requiring NHS bodies to issue an apology as part of the candour procedure. It is intended the regulations will require an apology to be made at the start of the process when the triggering of the duty is notified to the service user. It is important to note that, for these purposes, apologising is not the same as the body admitting the adverse outcome suffered by the service user was as a result of the negligence of the body as an adverse outcome can be attributed to many causes. By apologising at the start of the process it is hoped that the Body and the service user can maintain a good relationship as they follow the candour procedure and beyond.

Regulations made under section 4(3)(b) are intended to outline the requirements to be placed on an NHS body to provide support when notifying a service user the duty has been triggered. This provision aims to ensure that support is offered to a service user and that the support offered is appropriate to the severity of the incident and their needs; allowing the level of support to vary as required. This will align to the requirement to assign an appropriate nominated individual (a member of staff) when the duty is triggered (as covered under section 4(2)(b)) by describing their role in providing support to a service user.

Regulations made under section 4(3)(c) allow the Welsh Ministers to set out the records NHS bodies must keep in relation to their discharge of the duty. Accurate and appropriate record keeping supports necessary quality assurance mechanisms which are needed to identify areas for learning and improvement; linking to the reporting duties outlined in sections 6, 7 and 8 of the Bill.

Section 4(4) provides the Welsh Ministers with the ability to make any other provision in relation to the candour procedure as the Welsh Ministers consider appropriate. It

² National Patient Safety Agency. Being Open [Internet]. 2009. Available from: <https://www.hsj.co.uk/download?ac=1293677>

³ NHS Wales Shared Services Partnership. Paper prepared for NHS Directors of Finance Forum, 2016 - reduction of lower value claims for LHBs and NHS Trusts reaching litigation in Wales.

is intended to consult before making the regulations and it may be that the consultation process highlights further related provisions that are required in order to make the candour procedure fit for purpose. This provision allows for changes to the procedure or for additional elements to be added to the procedure; ensuring it remains appropriate, proportionate and deliverable in achieving the policy intent.

WHY THE REGULATIONS ARE REQUIRED

Consideration was given to setting out the precise detail of the procedure to be followed by NHS bodies on the face of the Bill. However, this would not provide sufficient flexibility to amend the procedure as required - increasing the risk of the procedure not being fit for purpose. For example, the detail may need to be amended to be responsive to changes in the models of care and working practices, to learn from the experience of users of the procedure and to take into consideration how the procedure operates in more complex or unusual cases.

The regulations will be developed through a process of consultation with stakeholders and will be reviewed as required. This process will allow for regulations to be amended as necessary to reflect best practice and lessons learned, and address any possible omissions.

In adopting this approach we were also mindful of the fact that the detail of the procedure for the duty of candour is also set out in regulations (as opposed to primary legislation) in other jurisdictions where the duty of candour applies.

For instance in England⁴ the procedure is set out in regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, as amended by the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015.

Similarly, in Scotland section 22 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 adopts a similar approach as whilst section 22 sets out a range of matters that may be included in the candour procedure, the detail of the procedure is, again, left to regulations⁵.

The negative procedure is used because the regulations will be of a technical nature.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

The regulations will be supported by guidance. It is the intention that guidance will also cover, amongst other things, instances where more than one provider has provided care to a single service user and more than one incident has occurred. The guidance will explain how we expect each NHS body involved in an “incident” will discharge its duty and to do this in respect of each incident.

⁴ See regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (SI 2014/) as amended by the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 (SI 2015/64)

⁵ The Duty of Candour Procedure (Scotland) Regulations 2018 (SI 2018/57).

The guidance will also consider scenarios when NHS bodies may wish to work together in discharging their duties jointly i.e. provide a single response to the service user or someone acting on their behalf.

3. Anticipated Timetable for Delivery

STATUTORY INSTRUMENT	ANTICIPATED WORK START DATE	ANTICIPATED DATE IN FORCE
Autumn 2021	Preparatory work will commence as the Bill progresses through the Assembly.	Spring 2022