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28 October 2021

Dear Huw

Thank you for your letter of 20 October seeking information and an update regarding the Legislative Consent Memorandum (LCM) for the UK Government Health and Care Bill. I have addressed your questions below.

**1. Please can you provide an update on these discussions, and provide the specific details on any amendments to the Bill which you have sought.**

Discussions with the UK Government have continued since the laying of the LCM on 1 September. I met with Minister Argar on 15 September and 13 October to discuss the Bill and our officials continue to work to try to find positions on the Bill clauses acceptable to both the Welsh Government and UK Government.

As set out in the LCM, two of my main areas of concern with the Bill are:

Firstly, the clauses where the UK Government is proposing that the Welsh Ministers are consulted before the Secretary of State exercises powers in relation to Wales in an area within devolved competence. The preferred approach of the UK Government for clauses of this nature is that the requirement for consultation of Welsh Ministers accompanied by a separate intergovernmental agreement setting out how that will work. That is not my preferred approach given that the agreements are not legally binding and can be disregarded by future Governments.

Secondly, the powers contained in a number of clauses for the Secretary of State to be able to make consequential amendments to provisions in a Measure or Act of Senedd Cymru. My officials have been working closely with Department for Health and Social Care (DHSC) officials exploring options to seek acceptable positions on these issues and I remain hopeful that such agreement can be reached.

There are also a number of areas of concern regarding specific clauses, including Clause 120 referred to in your letter. The issues and progress on these is as set out below:

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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.

## **Clause 85: Medicines information Systems**

I have a number of concerns regarding this clause, which provides for the Secretary of State to make regulations making provision about the establishment and operation of one or more UK-wide patient medicines registries. The purpose of these registries is to provide a source of evidence on the use, safety and effectiveness of medicines, and to improve patient safety.

### **Issue 1 – Overlap with data gathering in Wales**

While I am supportive of allowing routinely collected data to be included in registries for the purposes of improving the safety, quality and efficacy of human medicines, the purpose for which information can be collected under this clause is too broad, extending beyond safety matters and into areas within devolved competence, such as information relating to clinical decision making. The effect of the clause is that a broader range of information can also be collected by NHS Digital and not only information about medicines. This will result in NHS bodies, GPs, pharmacies, schools, and higher education in Wales being required to provide information to NHS Digital, potentially within areas of devolved competence. The introduction of these registries could also place a significant financial burden on the providers of health and education services in Wales, specifically for those contracted to provide primary care health services. The requirement to collect the relevant information could have an impact on the Primary Care service contracts in Wales and the subsequent financial burden being placed upon Welsh Government. I do not consider that it is necessary for NHS Digital, which is an England body, to establish a system for the whole of the UK. Wales has its own Digital Health Authority (Digital Health and Care Wales) with powers to collect the information from existing systems in Wales. Digital Health and Care Wales is responsible for health data in Wales and therefore could establish a system for Wales and contribute to the UK registry based on a set of agreed standards and specifications ensuring NHS Digital is only provided with the specific information on Welsh patients it needs for the specific purposes of the registries. I have therefore requested that UK Government amend the clause to place duties on the Welsh Ministers to enable them to set up equivalent systems, either through digital authorities in Wales or by nominating NHS Digital to set up a system on their behalf. This would avoid arrangements by-passing Welsh Ministers.

### **Issue 2 – Use of Data by Welsh Ministers**

There is no provision in the Bill to enable the data to be made available for use by the Welsh Ministers for purposes within their competence, for example clinical decision making.

### **Issue 3 – Inappropriate use of Welsh patient data**

Regulations made under this provision potentially enable a wide use of the information contained within these systems that may not be considered appropriate in relation to Welsh patients. In order to resolve these issues I have requested the Bill be amended to provide for an intermediary (NHS Wales) organisation to collect data on behalf of Welsh Ministers, removal of the specific element allowing Welsh citizens' data to be used for clinical decision making once provided to NHS Digital, and allowing for the provision of pseudonymised data to NHS Digital.

## **Issue 4 – Need for the Consent of Welsh Ministers to regulations**

As regulations impacting Wales can be made by the Secretary of State for Health under these powers, I requested the Bill be amended to include that regulations made under the powers provided to the Secretary of State under this clause should only be made with the consent of Welsh Ministers. If the Bill is amended, as I have indicated above, then the issue of the requirement for the consent of Welsh Ministers to regulations made under the provisions impacting on Wales would fall away. If the amendments are not however made then a consent requirement would remain my position.

Discussions on all the Medicines Information System issues are currently still on-going.

## **Clauses 86-92; Arm's Length Bodies Transfer of Functions**

These clauses create a general power in primary legislation for the Secretary of State to transfer or merge functions between specified Arm's Length Bodies and to abolish Arm's Length Bodies where all functions are transferred by way of regulations. Some of the Arm's Length Bodies in scope of the power undertake functions in Wales, Welsh Ministers have powers of direction in respect of some functions and Welsh Ministers have rights to appoint or nominate Welsh representation to them. Transferring or merging the functions of these bodies could therefore result in an erosion of Welsh Ministers' powers in relation to those bodies or impact on the functions of that body in Wales.

The main bodies of concern are:

- NHS Digital
- Health Research Authority
- Human Fertilisation and Embryology Authority
- Human Tissue Authority
- NHS Blood and Transplant
- NHS Business Services Authority.

The clauses also enable the Secretary of State to delegate specified functions to these Arm's Length Bodies. These specified functions are functions of the Secretary of State which relate to the health service in England or any other functions that the Secretary of State may provide for a Special Health Authority to exercise. However, reassurances have been provided that in relation to cross-border Special Health Authorities, such as NHS Blood and Transplant, this does not include functions that they are directed to exercise by the Welsh Ministers in relation to Wales.

## **Issue 1 – Provision of Consent in clause rather than Consult**

The clauses regarding the transfer of functions between specified Arm's Length Bodies provide for the Secretary of State to consult the Welsh Ministers on regulations made under clauses 87 or 88 if those regulations would apply in Wales. As stated above, I have requested that the Bill be amended to require that regulations made under the powers provided to the Secretary of State under this clause should be with the consent of Welsh Ministers in order to protect the devolution settlement.

## **Issue 2 – Power to make consequential amendments to Welsh legislation**

There is a power for the Secretary of State, when making regulations under clauses 87 or 88, to be able to make consequential amendments to provisions in a Measure or Act of Senedd Cymru.

## **Issue 3 – Secretary of State power to transfer property etc to Welsh Ministers**

Clause 90 provides the Secretary of State with the power to transfer property, rights and other liabilities to the Welsh Ministers or Welsh NHS Trusts. I have requested that Welsh Ministers and Welsh bodies are carved out of the Clause 90 provision and I am hopeful that this will happen.

Discussions on the other issues of concern in relation to Arm' Length Bodies are still continuing.

## **Clause 120: International healthcare arrangements**

Though international healthcare agreements are not devolved, the NHS in Wales has to manage incoming patients covered under all international healthcare arrangements. Any arrangements struck with other countries which are implemented under these provisions could lead to increased health tourism which could put pressure on, and impact the capacity of, our Local Health Boards.

## **Issue 1 – Provision of Consent in clause rather than Consult**

The main concern with Clause 120 is the requirement to only consult with the Welsh Ministers on draft regulations giving effect to international healthcare agreements. This means that should the Welsh Government have concerns regarding unreasonable or unfunded pressures on the NHS in Wales arising from such agreements, those concerns may not always be taken into account.

## **Issue 2 – Conferring functions on Welsh Ministers and Public Authorities in Wales**

The clause also enables the Secretary of State to confer functions on and/or delegate functions to Welsh Ministers and public authorities in Wales, when making regulations to make provision for the purpose of giving effect to healthcare agreements.

Discussions are continuing on the wording of these provisions that would address my key concerns and I am hopeful that a satisfactory position can be reached.

## **Clause 123: Regulation of health care and associated professions**

While the regulation of health professionals is reserved, the regulation of persons who are not professionals but who are groups of workers concerned with the physical or mental health of individuals falls within devolved competence. The clause would extend the power of the Secretary of State to regulate these additional groups of workers. UK Government officials have proposed that this clause be amended to include a requirement to consult the Welsh Ministers which is supported by a Memorandum of Understanding, should UK Government seek to regulate under section 60 of the Health Act 1999 in areas of devolved competence. I have requested that the Bill be amended

such that the Secretary of State would require the consent of the Welsh Ministers to such regulations. Positive discussions in this area are continuing.

### **Clause 125 and Schedule 16: Advertising of less healthy food and drink**

Whilst the substantive content of the clauses covering restrictions on the advertising of unhealthy food on a 4 nations basis is welcomed, there is consequential power included enabling the Secretary of State to amend Welsh legislation. As with the same provision in relation to Arm's Length Bodies, this is an issue of on-going discussion with DHSC. However it should be noted that this is an area of the Bill DHSC do not accept is devolved and do not agree should be subject to a requirement for the legislative consent of the Senedd.

### **Clause 130: Power to make consequential provision**

This clause gives the Secretary of State a broad consequential amendment power in relation to the Bill and allows an Act or Measure of the Senedd to be amended, repealed or revoked without any recourse to Welsh Ministers or provision enabling Welsh Ministers to exercise this power. Discussions on this matter are on-going.

### **Further Bill Amendments**

There are a number of other potential amendments to the Bill being drafted by the UK Government one of which, in relation to Medical Examiners (detailed below), has been requested by the Welsh Ministers. Should these amendments require the legislative consent of the Senedd then a supplementary LCM will be laid before the Senedd at the appropriate time.

### **Medical Examiners**

The UK Government has agreed, at my request, to table an amendment to Clause 124 of the Bill to amend section 19 of the Coroners and Justice Act 2009. This amendment is not being requested to address any issues of concern with the Medical Examiner provisions currently in the Bill which, as introduced, do not impact on devolved competence, but has been requested in order to better reflect the manner in which the Medical Examiner system has been developed to operate in Wales.

**2. You state that clause 120 (concerning International Healthcare Agreements) is one of the Bill's clauses which gives you concern as it could negatively impact NHS bodies in Wales.**

My concerns in relation to Clause 120 have been set out in in response to Question 1 above.

**a. Clause 120 of the Bill would constitute a departure from constitutional convention, by permitting the UK Government to implement international agreements that require changes to domestic legislation via subordinate legislation rather than by primary legislation (which provides better opportunities for parliamentary scrutiny). Clause 120 would introduce a new approach to the scrutiny of international healthcare agreements which excludes the Senedd from scrutiny of a devolved matter. What are your views on this specific aspect of clause 120?**

Whilst Welsh Government is not supportive of the principle of the use of Henry VIII powers in Bills, I consider this a matter for UK Parliament to consider in its scrutiny of this Bill. The role of Welsh Government is to seek to protect the devolved settlement where UK Bill proposals impact, or have the potential to impact, on it or on Welsh bodies.

Clause 120 does not per se introduce a new approach to the scrutiny of healthcare agreements which excludes the Senedd scrutiny of a devolved matter. International agreements are reserved and are binding on the UK as a whole to implement and observe irrespective of the legislation they are made under – and indeed can be entered into by the UK Government without making them under any specific legislation. With regard to healthcare agreements, there are a number of long-standing UK healthcare agreements in place with countries other than the EU which do not have a specific legislative basis and therefore have not been, nor necessarily will be, subject to Senedd scrutiny. Therefore whilst I have concerns about the implications of the use of the powers in Clause 120 for the Welsh NHS, I do not agree that the provisions in this Bill change the position on Senedd scrutiny of healthcare agreements, as currently there is no such automatic right.

To be clear, the provisions in this Bill will extend the current Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 to rest of the world countries. In some ways therefore by legislating in the area of rest of the world healthcare agreements, it has given the Senedd an opportunity to scrutinise such primary powers in an area where there previously was no such involvement of the Devolved Administrations. That said, I remain concerned about the ability in the Bill as introduced for the UK Government to make regulations giving effect to healthcare agreement that impact on Wales without the consent of Welsh Ministers. Discussions with DHSC on this matter to address my key concerns remain on-going and, as I have stated earlier, I am hopeful that a satisfactory position can be reached.

**b. Clause 120 also provides broad scope to the Secretary of State to make payments for healthcare that falls outside of an international healthcare agreement in “exceptional circumstances”, which is not defined by the Bill. Further, there are no limits on the amount or type of healthcare funded. What are your views on these matters?**

In my view this is a necessary power. The power will allow the Secretary of State to support UK nationals abroad where due to exceptional circumstances they require access to healthcare abroad but fall outside the scope of a reciprocal healthcare agreement. It is not envisioned that such a power would be regularly used. However it would not be prudent to limit the use of the power on the face of the Bill to specific circumstances, as the circumstances where this power might be required to be used may fall outside what could be predicted and thereby covered by the Bill provisions. But in any case these provisions do not extend to Welsh Ministers and the costs will fall solely to the UK Government to fund.

**3. Can you confirm that there are no restrictions on the face of the Bill preventing UK Ministers from using regulation-making powers in the Bill to amend the Government of Wales (Act) 2006?**

There are no such restrictions on the face of the Bill therefore in theory, the consequential powers could be used by UK Ministers to amend GOWA as they allow for the amendment of primary legislation, which includes a UK Act and GOWA is a UK Act. However, the powers are limited to consequential changes, thus any amendments would have to be consequential on the Bill provisions or regulations made under them. In the view of the Welsh Government it is unlikely that it could be argued that any substantive provision in GOWA would require amendment in consequence of this Bill.

**4. How concerned are you with clause 130 of the Bill, given that it provides the Secretary of State with regulation-making powers to make consequential provision, meaning it could be used to amend primary legislation made by the Senedd and subordinate legislation made by the Welsh Ministers?**

My concerns with regard to this clause are set out in the answer to Question 1 above. I would re-iterate that I remain in discussion with DHSC regarding these concerns exploring options to reach an acceptable position.

I trust this response will be helpful in the Committee's scrutiny of the LCM.

Yours sincerely



**Eluned Morgan AS/MS**  
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol  
Minister for Health and Social Services