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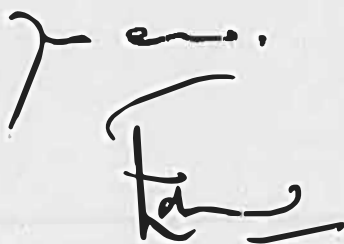
 November 2021

Dear *Russell*,

I would like to extend my apologies for not having replied to your correspondence dated 29th September. Due to a delay in your correspondence being processed by the department, your letter did not reach our office until now and, as such, has only just come to my attention. I am very sorry for this error and any inconvenience it has caused you. I am keen to do whatever I can to rectify this.

I am conscious that the 17th October deadline you state in your letter has passed, and that anything we can provide now may not be of use to the Senedd's Business Committee. Please do let me know if a formal response would still be helpful at this stage.

If it would be helpful, I would also be very happy to write to the Committee after the 15th November, by which point I hope we will have reached agreement on a package of amendments to be tabled at the Bill's Report Stage.



EDWARD ARGAR MP



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25 November 2021

Dear Russell

Thank you for your letter of the 29th of September, and apologies for the delay in responding to you. As you will appreciate, engagement has been ongoing with the Welsh Government to come to an agreed position on the areas within the Bill that engage the Legislative Consent process, and to reach agreement on a package of amendments. These amendments were accepted by the House of Commons at the Bill's Report Stage on 23rd November, and now form part of the Bill.

I hope the answers below will assist the Committee in its deliberation of the Bill and provide reassurance that the UK Government has engaged extensively with the Welsh Government over the relevant provisions.

Update on discussions with the Welsh Government

My officials have been in regular dialogue with officials in the Welsh Government about the Bill since early February and engaged positively and constructively on all the draft clauses when they were shared in advance of the Bill's introduction. Since September, I have also had a number of positive meetings with Minister Morgan to discuss specific concerns raised by the Welsh Government.

The amendments we agreed to make are the result of a collaborative effort by UK Government and Welsh Government officials over several months and I am delighted that we have managed to address the majority of issues raised by Minister Morgan.

Medicine Information Systems Clause, Clause 87

- **A requirement to consult with Scottish and Welsh Ministers before making regulations in relation to medicine information systems which relate to Scotland or Wales; and a requirement to consult with Scottish and Welsh Ministers before using any direction making power introduced in regulations in relation to medicine information systems where the direction relates to**

Scotland or Wales. Taken together, these amendments provide a statutory requirement to ensure Welsh and Scottish Ministers will have meaningful input into the establishment and operation of medicine information systems where they relate to Wales or Scotland, respectively.

- **An amendment to ensure that regulations will allow for an intermediary organisation to collect data within the devolved territories.** This amendment ensures that the Medicine Information System regulations must provide for information to be collected by Welsh and/or Scottish Ministers or a person designated by them if they include the provision of health information in relation to the Welsh or Scottish health services. The amendment also enables the regulations to confer powers or duties on Welsh and Scottish Ministers to ensure that this happens, should they be required for these purposes.
- **An amendment to the wording around the purposes for which the Medicine Information Systems can be established and operated in relation to clinical decision-making to make it clear that this is in relation to safety of clinical decision making.** This amendment clarifies the potential uses and restricts wider use of information to clinical decision making only, but it ensures that where a safety risk for an individual or group of patients is identified we can use that information to inform the use of the medicine in the clinical setting, for example to ensure risk-minimisation measures are followed.

Reciprocal Healthcare, Clause 122

- **An amendment to give the Devolved Administrations powers to make regulations in devolved areas, with the UK Government retaining the ability to make regulations to implement arrangements on their behalf.** This Amendment gives the Welsh Government and other Devolved Administrations a power to make regulations in respect of reciprocal healthcare agreements if it is within their devolved competency to do so. This will enable them to make regulations conferring functions to deliver any planned treatment obligations on a devolved public authority of their choosing. The Secretary of State will have a concurrent power to make regulations to implement reciprocal healthcare arrangements under the new section 2 of the 2019 Healthcare (European Economic Area & Switzerland) Arrangements Act.
- **Removal of Welsh, Scottish and Northern Irish ministers from the definition of public authorities.** This amendment will limit the Secretary of State's ability to confer functions to local health boards in Scotland and Wales only. The Welsh and Scottish Governments have agreed that the Secretary of State should be able to continue to confer functions on the local health boards in Scotland and Wales for the purpose of giving effect to a health agreement. This might be appropriate, for example, where the Devolved Administrations may agree that it would be more efficient for the Secretary of State to implement agreements on their behalf.

Professional Regulation, Clause 127

- **A requirement for the Secretary of State to obtain the consent of the Welsh Government when bringing into regulation in Wales a group of workers who are not professionals but who are concerned with the physical or mental health of individuals, under section 60 of the Health Act 1999.** This amendment introduces a requirement to obtain the consent of the Welsh Ministers before an Order in Council can be made under section 60 of the Health Act 1999, when it contains a provision which would be within the legislative competence of the Senedd. This would apply if we were seeking to bring into regulation in Wales a group of workers who are concerned with physical or mental health of individuals, but who are not generally regarded as a profession. The UK Government recognises the legislative competence of Senedd Cymru in this area and is respecting the devolution settlement in making this amendment.

ALB Transfer of Functions Power, Clause 89

- At present, we have been unable to reach agreement with all three Devolved Administrations over amendments to the ALB Transfer of Functions power. The UK Government has proposed a package of amendments. In correspondence from 17th of November Minister Morgan confirmed, subject to clarifications on the drafting, that if these amendments are made she would be content to recommend that legislative consent is granted for these provisions. However, since we do not at this stage have the agreement of all three Devolved Administrations to whom the amendments would apply, they have not been tabled. I remain hopeful that we will be able to reach agreement over the coming weeks ahead of the Bill's Committee Stage in the House of Lords.

In addition to the amendments outlined above, the Welsh Government requested that the application of two existing provisions in the Bill be extended to apply in Wales. The UK Government agreed to these requests.

Medical Examiners, Clause 128

- **Move the appointment ability for Medical Examiners from Local Health Boards to wider Welsh Health Bodies – mirroring the provisions in the Bill for English bodies.** The Bill already amends the statutory medical examiner system in England. At the request of the Welsh Government, this amendment further amends the statutory medical examiner system in the Coroners and Justice Act 2009 so that a Welsh NHS body may appoint medical examiners to scrutinise deaths, instead of solely local health boards.

Pharmacy Reimbursement of Vaccinations and Pandemic Products (New Clause)

- **Extend to Wales the amendment to allow for the supply of centrally purchased vaccines, pandemic treatments and associated products to community pharmacies without the need to then reimburse the pharmacies for them if these products were supplied free of charge.** The new clauses

amend both the NHS Act 2006 and NHS (Wales) Act 2006, enabling regulations to be made in respect of both England and Wales. This allows further exemptions from the obligation to reimburse pharmacies under the standard NHS arrangements when centrally stocked products have been supplied free of charge to community pharmacies without the need to reimburse them. It also allows the respective Ministers to create limited additional exemptions to the exemptions that can already be created by the existing regulation making powers, introduced in 2017, for unlicensed medicines, more commonly known as Specials.

In addition to the package of amendments above, I am pleased that my officials have been working with the Welsh Government, Scottish Government and Northern Ireland Executive to develop **Memorandums of Understanding for Reciprocal Healthcare (c.122) and the ALB Transfer of Functions Power (c.89)**, setting out how the respective consultation processes with the Devolved Administrations will work. These MoUs are still in the process of drafting but I am hopeful that they will be finalised as the Bill continues to progress through the UK Parliament.

Clause 134 (previously clause 130)

The UK Government has assessed that Clause 134 does not require an LCM. I understand that this is still being considered by the Welsh Government and on 17th of November Minister Morgan informed me that she will confirm the Welsh Government's position in due course.

Clause 134 enables the UK Government to make consequential amendments that might be necessary following the passage of the Bill, including to devolved legislation. The consequential amendments we envisage will include numerous amendments to secondary legislation as a consequence of the Bill's provisions, as such amendments were not included on the face of the Bill.

It is also prudent to retain a power to amend primary legislation in the event that anything has been missed. This would allow, for example, the updating of names of particular bodies – minor changes that, if left unaddressed, could prevent the effective operation of the legislation.

This type of power is quite common in a Bill as large as the Health and Care Bill, and there are many examples of similar powers in legislation already on the statute book and so I hope that the Committee are reassured that this is simply a useful power to ensure the statute book works effectively. The Welsh Government will obviously retain the ability to make such legislative changes to devolved legislation if they so choose.

The impact of the Bill on Wales

Whilst the majority of the measures in the Bill apply to England-only, we are also proposing changes that will bring enormous health benefits to the whole United Kingdom. The following provisions apply to Wales:

- ALB Transfer of Functions (Clause 89)
- Reciprocal Healthcare (Clause 122)
- Medicine Information Systems (Clause 87)
- Food Information for Consumers (Clause 131)
- Professional Regulation (Clause 127)
- Social Care Discharge to Assess (Clause 80)
- HFSS Advertising (Clause 129)

We also intend to bring forward amendments that the Welsh Government has requested which would mirror the steps we are taking for England, in the cases of Medical Examiners and Pharmacy Reimbursement of Pandemic Products.

My Department has worked very closely with officials, meeting on a weekly basis, to ensure that policies work for citizens in Wales as well as in England. Where any potential concerns have been raised by Welsh officials, DHSC has worked closely to provide the relevant legal and policy analysis to address them.

Most of the powers in the Bill that are relevant to Wales are enabling powers. If in future plans are developed to use these powers, impact assessments will be undertaken. If that is the case, we will consult the Welsh Government regarding those policies to ensure that the potential impact of provisions on NHS bodies in Wales are considered. The MoUs that are currently in development include a commitment to engagement with the Welsh Government at the earliest stages of the policy development and will allow potential impacts to be identified and addressed.

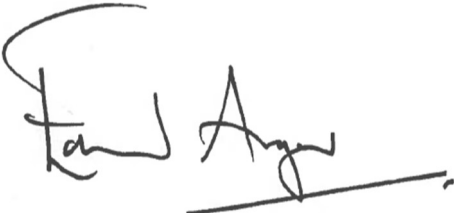
Financial Implications

The UK Government commits to consult with the Welsh Government on future potential cost implications in Wales when regulations are to be drafted and during the process of the Bill's implementation. We are fully committed to working with all of the Devolved Administrations to ensure smooth implementation of the provisions of the Bill and HMT have confirmed that the Barnett formula will apply, as set out in the Statement of Funding Policy.

Where relevant such as is the case with Medical Examiners and Reciprocal Healthcare, DHSC officials have provided a written explanation as to how the Welsh Government will be involved and consulted in the development of the plans.

I wrote to the Minister for Health about this on 15th of November. I have included that correspondence as an attachment to this letter.

I hope this update is useful to the Committee and would be happy to provide further information if it is needed.

Yours sincerely,


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15th November 2021

Dear *Eluned,*

I am writing with regard to the assurances you requested in our meeting on 13 October, on future funding implications for Wales of measures in the Health and Care Bill. As ever, I am grateful to your officials for their continuing collaboration with mine and thank them for providing a list of policy areas where the Welsh Government has identified potential concerns.

First of all, I would like to reiterate the UK Government's commitment to consult with the Welsh Government on future potential cost implications in Wales when regulations are to be drafted and during the process of the Bill's implementation. We are fully committed to working with all of the Devolved Administrations to ensure smooth implementation of the provisions of the Bill and HMT have confirmed that the Barnett formula will apply, as set out in the Statement of Funding Policy.

Below I have sought to address each of the areas set out by your officials.

Medicine Information Systems

The Medicine Information System clause provides enabling powers, and no new systems will be implemented until after regulations have been made. Once regulations have been made, the intention is to establish information systems in response to a clear public health need. Each will be a bespoke product established for specific purposes with different goals, operations, and needs, to closely monitor risks associated with the medicine in question. When need for a new registry is identified, we will work closely with you, and the other Devolved Administrations, to determine the operation, burden and cost, and to consider the funding model for the system to ensure it serves the right purpose. Every effort would be made to reduce costs by utilising data already collected as far as possible and developing tools to support bespoke data collection that can be used across the UK and in different settings.

It is worth noting that the main intent behind this policy is to use data to support the safe use of medicines, and it is known that the health and financial consequences of adverse drug

reactions can be significant. By developing a registry that can itself be used to minimise risks to patients we aim to improve the health of patients across the UK.

Reciprocal Healthcare

The amended Healthcare (European Economic Area & Switzerland) Arrangements Act will be forward-looking legislation, which will provide the UK Government with the appropriate legal basis to implement future reciprocal healthcare agreements.

Funding from the UK Government to the Devolved Administrations is determined through the Barnett formula and we are not envisaging a change to this arrangement through future reciprocal healthcare policy. However, I recognise your concerns around the impact future reciprocal healthcare agreements could have on the healthcare system in Wales, particularly in relation to non-maternity planned treatment and Overseas Visitor Charging. I hope that the explanation below will help explain the funding arrangements.

Firstly, I would like to assure you that it is our intention that the health care reimbursement process will continue to be administered by NHS Business Services Authority (NHSBSA) and the costs of all UK residents abroad will be covered by the Department of Health and Social Care, as is currently the case.

As the Government set out in the Health and Care Bill White Paper that was published in February 2021, it is our intention that future reciprocal healthcare agreements will predominantly facilitate access to medically necessary (e.g. emergency) care, similar to services that British nationals are currently able to access in the EU with their Global Health Insurance Card (GHIC). We therefore believe the impact on demand and healthcare tourism will be minimal.

Under current arrangements, there are many more visits from the UK to the EU than vice versa. In 2019 there were 25m visits by EU residents to the UK, compared to 67m visits by UK residents to the EU. For Wales, in 2019 there were approximately 14,000 EHIC claims in the EU, worth a value of £7m. This was paid by DHSC to Member States. In the same year, DHSC received an income of £0.34m from Member States, for treatments provided to EU-EHIC holders in Wales, which was used to offset the DHSC expenditure of Welsh residents accessing healthcare in the EU, with their EHIC.

Furthermore, residents of non-EU countries are already accessing such services in our healthcare systems in the UK when they travel, but a proportion of them do not repay their debt to the NHS before leaving the country. We believe that the introduction of a state-to-state reimbursement mechanism through reciprocal healthcare agreements, will improve cost recovery rates and will remove some of the burden on individual Trusts having to pursue individuals.

We do of course acknowledge that NHSBSA relies on individual Trusts reporting to them GHIC costs, which is the reason the UK Government reimburses reporting Trusts with 25% of the treatment costs provided to EU-issued EHIC holders, under the EHIC Incentive Scheme. In 2019/20, the UK Government paid approximately £9m to reporting Trusts, including from Wales, Scotland and Northern Ireland.

Finally, I would like to reassure you that before entering into the negotiation of reciprocal healthcare agreements, comprehensive impact assessments will be undertaken in collaboration with the Devolved Administrations to support transparency on cost, benefits

and inform evaluations of the impact across the UK. We believe that the risks of negative impacts on the healthcare system in Wales will be mitigated through the thorough engagement process set out in the Memorandum of Understanding that our officials are working on, detailing how Wales will be engaged early on and how you and your officials will be able to influence the policy development at every stage of the process.

I hope this provides you with reassurance that the UK Government will continue to cover the costs of reciprocal healthcare and that in future reciprocal healthcare agreements will only be entered if they benefit all the UK citizens.

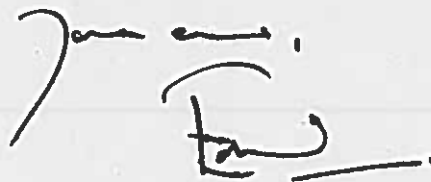
ALB Transfer of Functions Power

This is not a power to take away services that are currently provided by the relevant arm's length bodies that are in scope for this power. I want to reassure you that, following a transfer of function, all of the services currently provided to the people of Wales by DHSC arm's length bodies will continue. This includes the licensing of bodies and provision of guidance, as well as services provided to Welsh citizens. It should be noted that, as part of the policy development and consultation we would assess the impact on Welsh bodies and it may be that functions may be more effectively or efficiently delivered as a result of such a move – it is not just about potential costs.

Professional Regulation

Your officials also raised the question of whether the bringing into regulation in Wales of a group of workers who are not professionals but who are concerned with the physical or mental health of individuals, under section 60 of the Health Act 1999, could potentially result in increased costs for Welsh NHS bodies. As we have discussed, I hope to be able to table amendment that would make any such change subject to the consent of Welsh Ministers. Therefore, the question of funding would be subject to the discretion of Welsh Ministers. There are no current plans to use this power, however if in the future it was being considered, an assessment would be made in consultation with the devolved legislatures.

I would like to thank you and your officials once again for your constructive engagement throughout this process. I will be writing to you shortly seeking your agreement for the package of amendments to be tabled ahead of the Bill's Report Stage.



EDWARD ARGAR MP