



Russell George MS
Chair
Health and Social Care Committee

SeneddHealth@senedd.wales

2 February 2022

Dear Russell

Thank you for the Health and Social Care Committee's report on the Legislative Consent Memorandum (LCM) on the Health and Care Bill, laid 16 December 2021.

The position has been superseded by a number of amendments made to the Bill and two Supplementary LCMs laid on 17 December 2021 and 28 January 2022 respectively. This letter therefore reflects the latest position on the Bill in responding to the Committee's recommendations.

Firstly, I welcome the Committee's confirmation that it has no objection to the Senedd giving its consent to the inclusion in the Bill of:

- Clause 77 (formerly Clause 75) (Tidying up etc provisions about accounts of certain NHS bodies);
- Clause 80 (formerly Clause 78) (Hospital patients with care and support needs: repeals etc);
- Clause 87 (formerly Clause 85) (Medicines information systems) as amended by the House of Commons on 23 November 2021;
- Clause 142 (formerly clause 123) (regulation of health care and associated professions) as amended by the House of Commons on 23 November 2021; and
- Clause 146 (formerly Clause 127) (Food information for consumers - power to amend retained EU law).

I note the Committee's views regarding clauses 88-94 (formerly clauses 86-92): Arm's Length Bodies Transfer of Functions and I consider the amendments tabled by the UK Government on 24 January 2022 will, if passed, address the Committee's concerns regarding these clauses. The detail of the amendments is set out in the Supplementary Legislative Consent Memorandum (Memorandum No 3) laid on 28 January 2022.

Bae Caerdydd • Cardiff Bay
Caerdydd • Cardiff
CF99 1SN

Canolfan Cyswllt Cyntaf / First Point of Contact Centre:
0300 0604400

Gohebiaeth.Eluned.Morgan@llyw.cymru
Correspondence.Eluned.Morgan@gov.wales

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.

Please find my responses to your specific recommendations below.

Recommendations 1 and 2 - Clause 136 (formerly Clause 120): International Healthcare Arrangements

Recommendation 1

The Minister for Health and Social Services should make representations to the UK Government for an amendment to be brought forward to include on the face of the Bill a clear and proportionate test for what would qualify as an 'exceptional circumstance' for the purposes of the amount or type of healthcare that can be funded outside of an international healthcare agreement.

Response

Section 1 of the Healthcare (European Economic Area and Switzerland) Act 2019 (HEEASAA) currently provides the Secretary of State with a power to make payments, and arrange for payments to be made, in respect of the cost of healthcare provided in an EEA State or Switzerland.

Clause 136 (formerly clause 120) of the Bill will remove the power in section 1 of HEEASAA and replace it with regulation making powers enabling the Secretary of State to make regulations (a) for the purpose of giving effect to a healthcare agreement (including about making payments) between the UK and either a country or territory outside the UK or an international organisation, and (b) authorising the Secretary of State to make a payment in respect of healthcare provided otherwise than under a healthcare agreement, in a country or territory with which the UK has a reciprocal healthcare agreement, but only where the Secretary of State considers that the payment is justified by exceptional circumstances.

The purpose of the power enabling the Secretary of State to fund healthcare outside of an international healthcare agreement in exceptional circumstances is to assist the UK Government in supporting the healthcare needs of British residents when they are abroad in circumstances which might otherwise narrowly fall outside of a reciprocal healthcare agreement.

The UK Government has previously, for example, used existing powers under HEEASAA to provide crisis mental healthcare support to a minor in the EU where the Member State stated that the treatment was not covered under the European Health Insurance Card (EHIC) scheme. The UK Government has also funded treatment in the EU for twins with infantile haemangiomas who were born to UK residents but were unable to easily travel back to the UK due to COVID-19 travel restrictions and the risks of travelling at the time. They would not otherwise have been in scope of the planned treatment provisions in the EU reciprocal healthcare agreements as they could have received the treatment in the UK without undue delay had they been in the UK at the time.

Payments for healthcare outside the UK is a reserved matter because it concerns the welfare of people outside of the UK, and has no material bearing on, or connection to the domestic provision of healthcare in the UK; it is a matter of international relations whether and to what extent the UK decides to arrange and fund healthcare for people outside the UK.

Exceptional circumstances are likely to be those in which the refusal to fund healthcare treatment would result in unjustifiably harsh consequences for the individual such that the refusal of an application for funding would not be proportionate. Determining whether a payment is justified by exceptional circumstances will necessarily require a balance to be

struck between any competing public and individual interests involved. Attempting to define this further in primary legislation by reference to an amount or type of healthcare that can be funded would unduly restrict the Secretary of State's ability to exercise this discretion and hinder the ability to assist British residents when they most need it.

It is therefore my view that it is not appropriate to put a clear and proportionate test on the face of the Bill for what would qualify as an 'exceptional circumstance' for the purposes of the amount or type of healthcare that can be funded outside of an international healthcare agreement, as this could have a detrimental or limiting impact to provide support when needed.

Recommendation 2

Before the Senedd is asked to decide whether or not to give its consent to the inclusion in the Bill of clause 120 (now clause 136) (international healthcare agreements), the Minister for Health and Social Services should ensure that all Members have been provided with a copy of the final Memorandum of Understanding agreed between the UK Government and the Welsh Government in relation to the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019.

Response

I am pleased to enclose the reciprocal healthcare Memorandum of Understanding (MOU) with this letter for the consideration of the Committee, which has been revised in the light of the Bill provisions. The MOU has been agreed by all four nations. The Committee will wish to note that the wider linkages in relation to the new intergovernmental relations (IGR) governance arrangements have not yet been included in the MOU but are being considered. The MOU will be updated to reflect the new IGR arrangements in due course.

Recommendation 3 - Clause 142 (formerly Clause 123): Regulation of Healthcare and Associated Professions

Recommendation 3

The Minister for Health and Social Services should outline what analysis has been undertaken by the Welsh Government of the risks and benefits associated with regulating, or not regulating, senior health leaders and managers in Wales, and what the rationale is for her decision not to introduce such regulation.

Response

Clause 142 (formerly clause 123) has been amended to provide that no recommendation is to be made to Her Majesty to make an Order in Council under section 60 of the Health Act 1999 which relates to any group of workers, who are not professionals but who are concerned with the physical or mental health of individuals, where the Order contains provision that is within the legislative competence of the Senedd, unless the Welsh Ministers have consented to that provision.

No decision with regard to the regulation of these workers (which includes senior health leaders and managers in Wales) by Order in Council has yet been taken. Should the UK Government decide to regulate with regard to such professionals at a future point, if this was to also apply in Wales, then the Welsh Ministers will consider whether or not to consent to an Order making such provision. Such a decision would be supported by relevant evidence as to the risks, costs and benefits of applying the regulations within Wales.

We have no plans to regulate senior health leaders and managers in Wales and the configuration of the NHS within Wales make this an unlikely event in the future. The Department of Health and Social Care has also indicated that it has no specific plans to regulate this group of workers in the near future.

I am content this amendment addresses our concerns in respect of this provision and consequently I can now support this Bill clause.

Recommendation 4 - Clauses 149, 144 and 91 (formerly clauses 89, 125 and 130): Consequential Amendments to Senedd Legislation

Recommendation 4

Before the Senedd is asked whether to give its consent to the Bill, the Minister for Health and Social Services should provide a further update on her discussions with the UK Government on the consequential amendment powers in clauses 89, 125 and 130 of the Bill (as introduced), including whether, in her view, the assurances she has received from the UK Government in respect of the proposed use of the powers reduce the associated risks to acceptable levels.

Response

These clauses provide the Secretary of State with the powers, by regulation, to make provision which is consequential on the Bill. This includes provision that amends, repeals, revokes or otherwise modifies provision made by, or under, an Act or Measure of the Senedd.

As set out in the Supplementary LCM (Memorandum No. 3) laid on 28 January 2022, I and my officials have met with the Minister of State for Health, Edward Argar MP and his officials on a number of occasions to discuss these provisions. The UK Government is of the view that these are standard clauses and it is the case that Wales similarly takes powers in Senedd Acts to make consequential amendments to UK Government legislation.

UK Government officials have provided examples of how these powers may be used – the amendments likely would be of a minor nature, for example the changing of the name of an English organisation which is referred to in Senedd legislation where a transfer of functions has occurred. The Minister of State for Health has also given a written commitment to making a Dispatch Box Statement in relation to clauses 91 and 149, on how these powers might be used.

Clause 144 refers to Schedule 17 which amends the Communications Act 2003 to restrict the advertising of certain food and drink products in relation to the UK. The Clause and Schedule are covered in the first LCM on the Bill. Whilst this clause also contains provisions which enable consequential change to Senedd legislation, the UK Government has not identified this as a clause which requires the legislative consent of the Senedd and therefore will not include within the wording Dispatch Box Statement. However, on the basis of the assurances provided by the UK Government on the possible use of the powers, I accept the consequential amendments which might arise from clause 144 as an acceptable and minor constitutional risk.

We have agreed the wording of the Dispatch Box Statement with UK Government and the UK Government has committed to making the statement prior to the Legislative Consent Motion debate in the Senedd scheduled to take place on 15 February.

On the basis of the statement being made, and in the light of all of the assurances given by the UK Government, I regard the risk presented by the provisions now to be acceptable.

Recommendations 5 and 6 – Laying of LCMs and Content of LCMs

Recommendation 5

The Welsh Government should ensure that LCMs are normally laid no more than two weeks after a Bill is introduced in accordance with Standing Order 29.2(i). Should circumstances require a delay before an LCM is laid, the relevant Minister should write to the appropriate Senedd committees to provide an estimate of when the LCM will be brought forward.

Response

The Standing Order deadline is potentially achievable for Bills on which the Welsh Government and the UK Government have worked closely together and are in agreement. The “normally” qualification recognises the realities of what is a highly variable process. The increasing size and complexity of Bills and whether the UK Government has shared draft provisions, which is at its discretion, in advance of publication, can impact our timing for laying LCMs.

We will consider the amendment of the formal guidance for completing LCMs as part of our engagement with the Business Committee’s review of the LCM process to make writing to the Senedd Committees as described a requirement. In the meantime, when laying LCMs in more recent times, we have included explanation regarding any delay in laying within the LCM itself, to ensure Members are informed.

In addition where possible we have laid LCMs within the two week deadline to ensure the Senedd Committees have as much time as possible to scrutinise the LCM. For example I laid Supplementary LCM, Memorandum No. 3 on this Bill on 28 January, just four days after the tabling of UK Government amendments to the Bill.

Recommendation 6

The Welsh Government should ensure that the LCMs it lays provide the relevant committees with sufficient information about the Welsh Government’s position, its concerns, any remedies it is seeking, and such other matters as may be appropriate to enable full and effective scrutiny.

Response

When preparing LCMs, the Welsh Government seeks to fully inform Members of the extent of its position with regard to clauses engaging the LCM process, and of the position with regard to negotiations with the UK Government. However, as you will appreciate, there is a need to respect confidentiality, and we may not always be in a position to share all the information we receive. The negotiations with regard to this Bill have been successfully completed and the outcomes are set out in the Supplementary LCMs (Memorandum No 2 and Memorandum No 3) laid on the Bill.

I trust this response will be helpful in the Committee’s scrutiny of the Legislative Consent Memoranda on the Bill.

I am copying this letter to Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'M. E. Morgan'.

Eluned Morgan AS/MS

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



Huw Irranca-Davies MS
Chair
Legislation, Justice and Constitution Committee

2 February 2022

Dear Huw

Thank you for the Legislation, Justice and Constitution Committee's report laid on 3 December on the Legislative Consent Memorandum (LCM) for the Health and Care Bill (the Bill).

I note the Committee's comments on the first LCM laid on 1 September.

The position has been superseded by a number of amendments made to the Bill and two Supplementary LCMs laid on 17 December 2021 and 28 January 2022 respectively. This letter therefore reflects the latest position on the Bill in responding to the Committee's recommendations.

Please find my responses to your specific recommendations below

Recommendation 1 - Clause 87 (formerly Clause 85) (Medicines information systems)

Recommendation 1

The Minister should, in advance of the Senedd's debate on the relevant consent motion, provide further details of the intergovernmental discussions regarding clause 85 and confirm whether the amendments she has sought will be tabled to the Bill by the UK Government

Response

As set out in the Supplementary LCM (Memorandum No. 2) laid on 17 December, the UK Government has amended the Bill to address our concerns regarding clause 87 (formerly clause 85).

In relation to inappropriate use of data, the scope of the purposes for which medicine information systems regulations can be made under clause 87 is now limited. The clause now provides that provision in the regulations for a purpose in relation to clinical decision

Bae Caerdydd • Cardiff Bay
Caerdydd • Cardiff
CF99 1SN

Canolfan Cyswllt Cyntaf / First Point of Contact Centre:
0300 0604400

Gohebiaeth.Eluned.Morgan@llyw.cymru
Correspondence.Eluned.Morgan@gov.wales

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.

making can only be made where there is a connection with the safety of such decisions relating to human medicines.

Our concerns regarding the availability of data to the Welsh Ministers for purposes within devolved competence such as clinical decision making, and further concerns regarding the overlap of data collection for the purposes of the Registry with existing data gathering in Wales have also been addressed, as well as the commitment to consult on provisions made in regulations made under the provisions. The clause now provides that that secondary legislation made under it must provide for information to be collected by the Welsh Ministers or a person designated by them such as Digital Health and Care Wales (DHCW), subject to specified exceptions in that secondary legislation. The amendment ensures where appropriate, data remains available for use by the Welsh Ministers.

Finally, in addition to the safeguards agreed on the face of the Bill as introduced, there is now a requirement that the Welsh Ministers be consulted on any regulations or directions relating to medicine information systems which relate to Wales. This will be supported by a Memorandum of Understanding to be developed and agreed between the UK Government and the Devolved Governments. We have communicated to UK Government the need to develop this Memorandum as soon as possible with a view to it being in place before the provisions come into force.

Taken together I am content that the amendments made to these provisions address our key concerns and consequently I can now support this Bill clause.

Recommendations 2 and 3 - Clauses 88-94 (formerly Clauses 86-92): Arm's Length Bodies Transfer of Functions

Recommendation 2

The Minister should, in advance of the Senedd's debate on the relevant consent motion, provide further details of the intergovernmental discussions regarding clauses 86 to 92 and confirm whether the amendments she has sought will be tabled to the Bill by the UK Government.

Response

My two major concerns in this area have been addressed.

On 24 January 2022, the UK Government tabled an amendment providing for a statutory consent requirement, whereby the consent of the Welsh Ministers is required before the Secretary of State can make regulations under clauses 89 (formerly clause 87) (Power to transfer functions between bodies) or clause 90 (formerly clause 88) (Power to provide for exercise of functions of Secretary of State) where those regulations contain provision which would be within the legislative competence of the Senedd if contained in an Act of Senedd Cymru (and is not merely incidental to, or consequential on, provision which would be outside that legislative competence) or which modifies the functions of the Welsh Ministers (i.e. modifies their executive competence).

Further detail regarding this amendment is set out in the Supplementary LCM (Memorandum No. 3) laid before the Senedd on 28 January 2022.

With regard to my concern about the ability of the Secretary of State to transfer property, rights and other liabilities from Arm's Length Bodies to the Welsh Ministers, Welsh NHS Trusts and Wales-only Special Health Authorities in clause 92 (formerly clause 90), to resolve this, the UK Government also tabled, on 24 January, amendments removing the

Welsh Ministers, Welsh NHS Trusts and Wales-only Special Health Authorities from the list of “appropriate persons” in the clause, thus fully addressing our concerns in this area.

In my view, my concern regarding clause 91, which provides the Secretary of State with the power to, by regulations, make provision which is consequential on clauses 88 or 90 (formerly clauses 86 and 88) of the Bill, has been addressed by the UK Government as set out in the response to Recommendation 8, below.

Recommendation 3

The Minister should seek an amendment to the Bill to address her concerns regarding clause 87 to the effect that the Secretary of State cannot use the powers therein to transfer and/or delegate functions in relation to Special Health Authorities, where those functions were directed by the Welsh Ministers in relation to Wales.

Response

As set out in my response to Recommendation 2, above, subject to the passing of the UK Government amendments laid on 24 January, this power can only be exercised with the consent of the Welsh Ministers, thus fully addressing our concerns in this area.

Recommendations 4 and 5 - Clause 136 (formerly Clause 120): International Healthcare Arrangements

Recommendation 4

The Minister should, in advance of the Senedd’s debate on the relevant consent motion, provide the Committee and all Senedd Members with a copy of the final Memorandum of Understanding (MoU) in place between the Welsh and UK Government’s in relation to the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019, and confirm that the text of the MoU reflects the final, limited scope of the Bill as agreed by the UK Parliament

Response

I am pleased to enclose the reciprocal healthcare Memorandum of Understanding (MOU) with this letter for the consideration of the Committee, which I can confirm reflects the Bill provisions as amended on 23 November 2021. The MOU has been agreed by all four nations. The Committee will wish to note that the wider linkages in relation to the new intergovernmental relations (IGR) governance arrangements have not yet been included in the MOU but are being considered. The MOU will be updated to reflect the new IGR arrangements in due course.

Recommendation 5

The Minister should seek an amendment to the Bill to the effect that a clear and proportionate test for what qualifies as an ‘exceptional circumstance’ in clause 120 is included on the face of the Bill.

Response

Section 1 of the Healthcare (European Economic Area and Switzerland) Act 2019 (HEEASAA) currently provides the Secretary of State with a power to make payments, and arrange for payments to be made, in respect of the cost of healthcare provided in an EEA State or Switzerland.

Clause 136 (formerly clause 120) of the Bill will remove the power in section 1 of HEEASAA and replace it with regulation making powers enabling the Secretary of State to make regulations (a) for the purpose of giving effect to a healthcare agreement

(including about making payments) between the UK and either a country or territory outside the UK or an international organisation, and (b) authorising the Secretary of State to make a payment in respect of healthcare provided otherwise than under a healthcare agreement, in a country or territory with which the UK has a reciprocal healthcare agreement, but only where the Secretary of State considers that the payment is justified by exceptional circumstances.

The purpose of the power enabling the Secretary of State to fund healthcare outside of an international healthcare agreement in exceptional circumstances is to assist the UK Government in supporting the healthcare needs of British residents when they are abroad in circumstances which might otherwise narrowly fall outside of a reciprocal healthcare agreement.

The UK Government has previously, for example, used existing powers under HEESAA to provide crisis mental healthcare support to a minor in the EU where the Member State stated that the treatment was not covered under the European Health Insurance Card Scheme. The UK Government has also funded treatment in the EU for twins with infantile haemangiomas who were born to UK residents but were unable to easily travel back to the UK due to COVID-19 travel restrictions and the risks of travelling at the time. They would not otherwise have been in scope of the planned treatment provisions in the EU reciprocal healthcare agreements as they could have received the treatment in the UK without undue delay had they been in the UK at the time.

Payments for healthcare outside the UK is a reserved matter because it concerns the welfare of people outside of the UK, and has no material bearing on, or connection to the domestic provision of healthcare in the UK; it is a matter of international relations whether and to what extent the UK decides to arrange and fund healthcare for people outside the UK.

Exceptional circumstances are likely to be those in which the refusal to fund healthcare treatment would result in unjustifiably harsh consequences for the individual such that the refusal of an application for funding would not be proportionate. Determining whether a payment is justified by exceptional circumstances will necessarily require a balance to be struck between any competing public and individual interests involved. Attempting to define this further in primary legislation by reference to an amount or type of healthcare that can be funded would unduly restrict the Secretary of State's ability to exercise this discretion and hinder the ability to assist British residents when they most need it.

It is therefore my view that it is not appropriate to put a clear and proportionate test on the face of the Bill for what would qualify as an 'exceptional circumstance' for the purposes of the amount or type of healthcare that can be funded outside of an international healthcare agreement as this could have a detrimental or limiting impact to provide support when needed.

Recommendation 6 - Clause 142 (formerly Clause 123): Regulation of Healthcare and Associated Professions

Recommendation 6

The Minister should, in advance of the Senedd's debate on the relevant consent motion, provide further details of the intergovernmental discussions regarding clause 123 and confirm whether the amendment she has sought will be tabled to the Bill by the UK Government.

Response

I can confirm that the amendment we sought was achieved and the Bill amended so as to require the consent of the Welsh Ministers to an Order in Council made under section 60 of the Health Act 1999, which makes provision that is within the legislative competence of the Senedd and brings into regulation a group of workers who are not professionals, but who are concerned with the physical or mental health of individuals.

Further detail of the amendment is set out in the Supplementary LCM laid before the Senedd on 17 December 2021.

Recommendation 7 - Clause 144 and Schedule 17 (formerly Clause 125 and Schedule 16): Advertising of Less Healthy Food and Drink

Recommendation 7

The Minister should, in advance of the Senedd's debate on the relevant consent motion, provide further details of the intergovernmental discussions regarding clause 125 of and Schedule 16 to the Bill.

Response

I set out in my letter of 28 October 2021 to the Committee that whilst the substantive content of the clauses covering restrictions on the advertising of unhealthy food on a four nations basis is welcomed, there is consequential power included enabling the Secretary of State to amend Welsh legislation.

It should be noted that this is an area of the Bill which the UK Government does not accept is devolved and therefore does not agree should be subject to a requirement for the legislative consent of the Senedd.

However, as set out in the response to Recommendation 8, below, on the basis of the assurances provided by the UK Government on the possible use of the powers, we accept the consequential amendments which might arise from clause 144 (formerly clause 125) as an acceptable and minor constitutional risk.

Recommendation 8 - Clauses 149, 144 and 91 (formerly clauses 89, 125 and 130): Consequential Amendments to Senedd Legislation

Recommendation 8

The Minister should seek an amendment to the Bill to the effect that the powers in the Bill cannot be used by UK Ministers to make regulations that amend the Government of Wales Act 2006.

Response

These clauses provide the Secretary of State with the power, by regulations, to make provision which is consequential on the Bill. This includes provision that amends, repeals, revokes or otherwise modifies provision made by, or under, an Act or Measure of the Senedd.

As set out in the Supplementary Legislative Consent Memorandum (Memorandum No. 3) laid on 28 January 2022, I and my officials have met with the Minister of State for Health, Edward Argar MP and his officials on a number of occasions to discuss these provisions. The UK Government is of the view that these are standard clauses and it is the case that Wales similarly takes powers in Senedd Acts to make consequential amendments to UK Government legislation.

UK Government officials have provided examples of how these powers may be used – the amendments likely would be of a minor nature, for example the changing of the name of an English organisation which is referred to in Senedd legislation where a transfer of functions has occurred. The Minister of State for Health has also given a written commitment to making a Dispatch Box Statement in relation to clauses 91 and 149, on how these powers might be used. (As advised in response to Recommendation 7 above, the UK Government has not identified clause 144 as requiring the legislative consent of the Senedd and therefore will not include in the Dispatch Box Statement).

We have agreed the wording of the Dispatch Box Statement with UK Government and the UK Government has committed to making the statement prior to the Legislative Consent Motion debate in the Senedd scheduled to take place on 15 February.

On the basis of the statement being made, and in the light of all the assurances given by the UK Government, I regard the risk presented by the provisions now to be acceptable.

I trust this response will be helpful in the Committee's scrutiny of the Legislative Consent Memoranda on the Bill.

I am copying this letter to Russell George MS, Chair of the Health and Social Care Committee.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'M. E. Morgan'.

Eluned Morgan AS/MS

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

**MEMORANDUM OF UNDERSTANDING BETWEEN THE UK GOVERNMENT
SECRETARY OF STATE FOR THE DEPARTMENT OF HEALTH AND SOCIAL CARE
AND THE SCOTTISH MINISTERS, THE WELSH MINISTER FOR HEALTH AND SOCIAL SERVICES,
AND THE MINISTER OF HEALTH FOR NORTHERN IRELAND (THE "DEVOLVED GOVERNMENTS")**

**In Respect of the Consultation Process for International Healthcare Agreements and their
Implementation**

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A. INTRODUCTION

1. Overview and Scope

- 1.1 This Memorandum sets out the understanding of the United Kingdom (UK) Government Secretary of State for the Department of Health and Social Care (DHSC) and the Scottish Ministers, the Welsh Minister for Health and Social Services, and the Minister of Health for Northern Ireland ("the Devolved Governments"), on the Healthcare (International Arrangements) Act 2019 (HIAA). It sets out the arrangements for consultation and meaningful engagement in the formulation, negotiation, and implementation of new, revised and updated international reciprocal healthcare agreements, which go further than the consultation duty under section 5 of HIAA (see para 1.3 below).
- 1.2 The implementation of international reciprocal healthcare agreements, which include reimbursement and the exchange of data, is enabled by HIAA. Sections 2 and 2A of HIAA confer powers on the Secretary of State and Ministers in the Devolved Governments to make regulations for the purpose of giving effect to international reciprocal healthcare agreements. The power to make regulations is conferred on Ministers within the Devolved Governments where it would be within their devolved competence to make such provision.
- 1.3 This Memorandum also sets out how the Secretary of State will meet the legal requirement to consult with the Devolved Governments before making regulations under section 2 that contain provisions within the legislative competence of the devolved legislatures. However, the UK Government will

proceed in accordance with the convention that the UK Parliament would not normally legislate with regard to devolved matters except with the agreement of the devolved legislature.

1.4 This Memorandum does not create any additional legally enforceable rights and obligations between the parties. Nothing in this Memorandum should be construed as conflicting with the Belfast Agreement.

Responsibilities for Negotiating and Delivery of International Reciprocal Healthcare Agreements

1.5 The UK Government is responsible for international relations and has overall responsibility for concluding treaties and other international agreements on behalf of the United Kingdom.

1.6 The implementation of international healthcare obligations will usually be within the devolved competence of the Devolved Governments when the obligations relate to devolved healthcare provision within those countries.

2. Overarching Principles

2.1 DHSC and the Devolved Governments are committed to delivering collectively a reciprocal healthcare policy that works for residents throughout the UK as a whole in order to realise the broad benefits of international reciprocal healthcare agreements.

2.2 The arrangements set out in this Memorandum of Understanding will be underpinned by the principles of open communication, consultation, and cooperation. DHSC and the Devolved Governments are committed to making representations to each other as necessary in sufficient time for those views or concerns to be fully considered.

2.3 DHSC and the Devolved Governments recognise the importance of ensuring international reciprocal healthcare policy alignment for all healthcare systems across the UK and will work closely to develop and maintain a cohesive international reciprocal healthcare system that delivers for all UK residents. At the beginning of each stage of the process, DHSC and the Devolved Governments will agree a feasible timetable for all parties.

2.4 For those negotiations where DHSC is not the lead Government Department, DHSC and the Devolved Governments will proceed on the principles set out in this Memorandum of Understanding on specific international reciprocal healthcare elements.

B. CONSULTATION PROCESS – POLICY AND AGREEMENTS

3. Policy Mandate and Formation

Strategy Formulation

3.1 This Memorandum establishes arrangements (Annex A – Stage 1) for collaborative policy development and analysis where responsibility for implementation of those policies is within devolved competence. These arrangements provide a vehicle for meaningful engagement on policy proposals to take into negotiations. The arrangements will apply to the formation of overarching policy and model agreements as well as to individual policy mandates for reciprocal healthcare agreements with third countries. These arrangements will apply to any proposals for the review or amendment of implemented healthcare agreements with a view to reaching consensus by all parties on the proposed action. The Governments recognise that cooperation is necessary to meet their respective policy objectives.

3.2 DHSC will consult the Devolved Governments in writing where policy areas engage or have the potential to engage devolved competence. In addition, to support the effective implementation of

international healthcare agreements, DHSC will engage with the Devolved Governments on the full scope of any future international healthcare agreements to ensure that healthcare provisions work optimally across the whole of the UK. Consultation will be as early as possible and at a formative stage of policy development, as officials start to consider policy proposals, political steers, or third country requests for reciprocal healthcare agreements. The Devolved Governments will respond in writing, by an agreed date whenever possible, to DHSC setting out their views and any concerns about what is proposed on behalf of their Ministers and Executive. The Devolved Governments will be sent copies of papers and be invited to fully participate in meetings on subjects in which they have a devolved policy interest. Given the complexity of agreements, the strategy formulation will include engagement with all key partners as outlined in Annex A - Stage 1.

3.3 The arrangements will include regular informal and working level engagement between officials and Ministers to discuss policy proposals on the strategic direction for new international reciprocal healthcare agreements, or for proposals to renegotiate existing international reciprocal healthcare agreements and any projected impact assessments of those proposals. DHSC will arrange a regular international reciprocal healthcare meeting with the Devolved Governments on the issues, to be held with a frequency agreed with the Devolved Governments. DHSC will ensure that the Devolved Governments are given as much time as possible to properly consider proposals and feedback their views.

3.4 In order to enable each Government to operate effectively, the Governments will aim to provide each other with full and open access to policy information, for example data on S2 planned treatment, that may be requested where reasonable and appropriate. The Devolved Governments will be invited to contribute to impact assessments, on areas of devolved competence, which will be shared to support transparency on cost and benefits and inform evaluations of impact across the UK. The emphasis will always be on exchanging information where this proves possible to ensure a consistent approach to reciprocal healthcare policy and consideration of impact.

3.5 There will always be discussions between DHSC and Devolved Government officials in the first instance to reach a view on the policy before DHSC and Devolved Government officials put advice to their respective Ministers. DHSC officials will clearly identify where the views of the Devolved Government Ministers are still pending in their advice to DHSC Ministers. DHSC officials will ensure that the views of the Devolved Government Ministers are represented to DHSC Ministers in a timely manner, as soon as these are known. DHSC Ministers will write to Devolved Government Ministers to set out the policy proposals they endorse, giving them a reasonable period to respond, in order to build consensus on the direction to be taken in negotiations. Ministers from the Devolved Governments will provide their responses to DHSC Ministers by an agreed date whenever possible.

Agreement of Negotiating Mandate

3.6 All Devolved Governments will have the opportunity to influence the overall objective and shape of the mandate, noting this may be subject to change. As at Stage 1 (Annex A), the Devolved Governments will be sent copies of papers as early as possible and be invited to fully participate in meetings to build consensus on the negotiating mandate with regular informal and working level engagement between officials and Ministers to discuss policy proposals. Discussions between officials will be arranged with a frequency agreed with the Devolved Governments and depending on the timeframes for negotiations.

3.7 DHSC will share draft mandate text with the Devolved Governments for consultation and comment, prior to policy mandates going through cross UK Government write round and before publication. This will ensure appropriate consideration to the views of the Devolved Governments and that the negotiation mandates are acceptable to all parts of the UK (Annex A - Stage 2).

3.8 The Governments agree to share their respective legislative requirements at an early stage in the policy development process to provide for a common understanding of what will be necessary for implementation of a UK-wide agreement, to ensure transparency and timely consideration to feed into negotiations. This will be discussed by policy officials with policy and legal teams providing assurance on necessary implementation steps.

4. Negotiations and Drafting of International Agreements

- 4.1 DHSC will consult the Devolved Governments about the formulation of the UK Government's position for international reciprocal healthcare negotiations and any resulting deviations to the mandate where this has, or may have, an impact on devolved responsibilities. In such cases the Devolved Governments will be given early sight of evolving negotiating positions, with a reasonable period for consultation and comment, in order to reflect the views of the Devolved Governments in determining the approach for handling discussions. The Devolved Governments will respond with any concerns by an agreed date whenever possible.
- 4.2 Where there are deviations to the mandate DHSC officials will write to the Devolved Governments setting out the deviations for their review and consideration where this has, or may, impact on devolved responsibilities. Concession requests will be considered at official level in the first instance, with advice being put to DHSC Ministers and Devolved Government Ministers at the same time. DHSC will clearly identify where the views of the Devolved Government Ministers are still pending and will ensure that the views of the Devolved Government Ministers are represented to DHSC Ministers in a timely manner, as soon as these are known. Ministers from the Devolved Governments will provide any comments by an agreed date whenever possible. DHSC Ministers will consider any representations made and keep Devolved Government Ministers informed of any decisions by an agreed date whenever possible.
- 4.3 DHSC will provide regular updates to the Devolved Governments on the progress of negotiations including tracking documents and timelines (Annex A - Stage 3).
- 4.4 Once agreement with the third country has been reached in principle, advice will be provided to Ministers and the Devolved Governments on the final agreement. The legal text is the final output of the negotiations and will be drafted to reflect the policy proposals as they are developed (Annex A - Stage 4). DHSC will always seek to find consensus that the agreement reflects the policy position and assessment of implications and their suitability for implementation across the UK.

5. Ministerial Engagement

- 5.1 Engagement between Ministers may take place at any point throughout the consultation process set out in this Memorandum of Understanding upon request of any of the Ministers at DHSC or the Devolved Governments. DHSC and the Devolved Governments are committed to constructive and proportionate engagement with Ministers through the optimal engagement forum and commit to arranging ministerial discussions if required and desirable, coupled with formal written communications at key points on all negotiations.

6. Dispute Resolution

- 6.1 While the aim of this Memorandum of Understanding is to facilitate the consultation process on reciprocal healthcare agreements and section 2A of the HIAA provides powers for the Devolved Governments to introduce regulations when deemed necessary, recognising devolved competency, in circumstances where agreement cannot be reached, all efforts should be made to resolve disputes by an agreed date through the following process where possible:
- i. In the first instance, concerns will be raised informally and at working level between policy officials. All officials should fully commit themselves to achieving agreement if possible.
 - ii. Where officials cannot reach an agreement, the issue should be brought to the attention of more senior officials. Senior officials should make every effort to resolve the problem without the need for ministerial engagement.
 - iii. If no agreement is reached at official level, concerns should be raised at ministerial level. The final escalation point will be to Ministers.
- 6.2 The UK Government will proceed in accordance with the convention that the UK Parliament would not normally legislate with regard to devolved matters except with the agreement of the devolved legislature. In the event that no resolution can be found, there will be an exchange of letters between

Ministers. This would provide the opportunity for a Devolved Government to set out its position, and for the Secretary of State to explain the reasons for the final position and how the UK Government has sought to reach agreement with the Devolved Governments. If the Secretary of State decides to proceed without resolution and guided by the principles set out in this Memorandum, the exchange of letters should be made available to both Houses of Parliament.

6.3 The process outlined above gives the Governments an opportunity to resolve disputes, but there is not a formal obligation to follow this process.

7. Confidentiality

7.1 Each Government will wish to ensure that the information it supplies to others is subject to appropriate safeguards in order to avoid prejudicing its interests. Complete confidentiality is often essential in matters touching on international relations and in formulating a UK policy position. The effectiveness of arrangements agreed under this Memorandum of Understanding will rely on mutual respect for the confidentiality of information exchange. The Governments accept that in certain circumstances a duty of confidence may arise and will between themselves respect legal requirements of confidentiality. Each Government can only expect to receive information if it treats such information with appropriate discretion and not share anything publicly without agreement of all parties.

7.2 There will also be a common approach to the classification and handling of sensitive material. Information will be shared at the appropriate classification level decided by the administration providing the information. Each Government will treat information which it receives in accordance with the restrictions specified. In the event that a Government is subject to a legal obligation to disclose information, for example a freedom of information request, the Governments will consult each other and assist the Governments in complying with their legal obligations.

C. CONSULTATION PROCESS - IMPLEMENTATION AND REVIEW

8. Regulations under HIAA

8.1 In line with the principles set out above, it is necessary to ensure a transparent and consistent engagement process between DHSC and the Devolved Governments to support the making of regulations under section 2 and 2A of HIAA.

8.2 Meetings will be held as early as possible during the process set out in Section B to agree how international obligations in areas of devolved competence should be implemented and determine a feasible timetable for all parties. This might include Ministers in the Devolved Governments making regulations or alternatively the Secretary of State making regulations on behalf of the Devolved Governments.

8.3 The Devolved Governments will notify DHSC how they wish to proceed in a timely manner to ensure obligations can be implemented by any agreed deadline in an international reciprocal healthcare agreement. DHSC do not intend to exercise section 2 powers to make regulations in areas of devolved competence without the agreement of the relevant Devolved Governments.

8.4 When making regulations in areas of devolved competence, officials and Ministers agree to share information, including draft regulations and proposed timetables, to ensure obligations in international agreements are implemented coherently and on time. The timetable for delivery of the regulations will be agreed in advance with the Devolved Governments. The Devolved Governments will notify the UK Government and each other of any potential impacts on the delivery timetable for example, minimum notification periods, legislative process/protocol and translation requirements. Drafted regulations will be shared in a timely manner to provide an opportunity for consideration and comment. Engagement must be as early as possible to allow time for ministerial and Parliamentary

consideration. Officials will collectively agree when to share a draft of the regulations to which HIAA applies with their respective Ministers.

8.5 Section 2A of the HIAA provides powers to the Devolved Governments to make regulations to implement reciprocal agreements in their respective countries if provision is within the devolved competence of the Devolved Government. If the UK Government has concerns about any delay in the implementation of international obligations, or the Devolved Governments fail to make regulations within the agreed timeframe, or in the event that agreement on the regulations cannot be reached, the process set out above (6. Dispute Resolution) will be followed. If no resolution is found, there will be an exchange of letters between Ministers. This would provide the opportunity for a Devolved Government to set out its position, and for the Secretary of State to explain the reasons for the final form of the regulations and how the UK Government has sought to reach agreement. If the Secretary of State decides to proceed without resolution and guided by the principles set out in this Memorandum, the exchange of letters will be made available to both Houses of Parliament and the Devolved Governments will bring them to the attention of their respective parliaments.

9. Operational Implementation

9.1 Before an agreement comes into force the Governments should demonstrate operational and communication readiness. Officials from all Governments commit to consult on and set out a timescale for implementation.

9.2 DHSC and the Devolved Governments will ensure a cooperative and coordinated approach to the operational implementation of reciprocal healthcare policy that works for all parts of the UK. This may for example include developing and coordinating bespoke packages of communications to inform individuals and healthcare providers about new reciprocal healthcare agreements.

9.3 All four Governments will work together, where appropriate, on matters of mutual interest to provide the most effective outcomes for citizens of the UK and promote equity of treatment across the UK. Various public bodies deal with reciprocal healthcare matters within the responsibilities both of the UK Government and the Devolved Governments. The UK Government and Devolved Governments affirm their commitment to work together, where appropriate, to ensure that such bodies continue to operate effectively.

10. Review

10.1 This Memorandum of Understanding will be reviewed no later than 24 months after the date it is agreed, with any subsequent reviews to be scheduled in the course of the review. This review will be conducted by officials and agreed by Ministers.

10.2 The Governments recognise that there may be a need from time to time for some adjustment to be made to the Memorandum of Understanding, for example, in response to new issues or in the light of any changes to concordats and bilateral relations more generally. The Governments agree that there should be mechanisms in place to review the operation of the settlements and for adjustments to be agreed.

D. DATA SHARING

To support ongoing collaboration between all parts of the UK, a separate Memorandum of Understanding will cover data sharing.

E. SIGNATORIES

Minister of State for Health, UK Government

Minister for Health and Social Services, Welsh Government

Cabinet Secretary for Health and Social Care, Scottish Government

Minister of Health, Northern Ireland Department of Health

ANNEX A

Reciprocal Healthcare International Negotiations Process Map

Reciprocal Healthcare International Negotiations Process Map

