



Huw Irranca-Davies AS  
Cadeirydd y Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

2 Chwefror 2021

Annwyl Huw

Diolch am adroddiad y Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad, a osodwyd ar 3 Rhagfyr, ar y Memorandwm Cydsyniad Deddfwriaethol ar gyfer y Bil Iechyd a Gofal ('y Bil').

Rwy'n nodi sylwadau'r Pwyllgor ynglŷn â'r Memorandwm Cydsyniad Deddfwriaethol cyntaf a osodwyd ar 1 Medi.

Disodlwyd y safbwynt gan nifer o ddiwygiadau a wnaed i'r Bil a dau Femorandwm Cydsyniad Deddfwriaethol Atodol, y naill wedi'i osod ar 17 Rhagfyr 2021 a'r llall ar 28 Ionawr 2022. Mae'r llythyr hwn, felly, yn adlewyrchu'r safbwynt diweddaraf ar y Bil wrth ymateb i argymhellion y Pwyllgor.

Mae fy ymatebion i'ch argymhellion penodol i'w gweld isod.

### **Argymhelliad 1 - Cymal 87 (Cymal 85 gynt) (Systemau gwybodaeth meddyginiaethau)**

#### Argymhelliad 1

Dylai'r Gweinidog, cyn y cynhelir dadl y Senedd ar y cynnig cydsyniad perthnasol, ddarparu manylion pellach am y trafodaethau rhynglywodraethol a gafwyd ynghylch cymal 85, a dylai gadarnhau a fydd y diwygiadau y mae wedi'u ceisio yn cael eu cyflwyno i'r Bil gan Lywodraeth y DU.

#### Ymateb:

Fel y nodir yn y Memorandwm Cydsyniad Deddfwriaethol Atodol (Memorandwm Rhif 2) a osodwyd ar 17 Rhagfyr, mae Llywodraeth y DU wedi diwygio'r Bil i fynd i'r afael â'n pryderon ynghylch cymal 87 (cymal 85 gynt).

Mewn perthynas â gwneud defnydd amhriodol o ddata, mae cwmpas y dibenion y gellir gwneud rheoliadau systemau gwybodaeth meddyginiaethau ar eu cyfer o dan gymal 87 yn awr yn gyfyngedig. Mae'r cymal yn awr yn darparu mai dim ond os oes cysylltiad â diogelwch penderfyniadau o'r fath sy'n ymwneud â meddyginiaethau dynol y gellir gwneud darpariaeth yn y rheoliadau at ddibenion sy'n ymwneud â gwneud penderfyniadau clinigol.

Aed i'r afael hefyd â'n pryderon ynghylch argaeledd data i Weinidogion Cymru i'w defnyddio at ddibenion sydd o fewn cymhwysedd datganoledig, megis gwneud penderfyniadau clinigol, a phryderon pellach ynghylch y gorgyffwrdd rhwng casglu data at ddibenion y Gofrestrfa a chasglu data presennol yng Nghymru, yn ogystal â'r ymrwymiad i ymgynghori ar ddarpariaethau a wneir mewn rheoliadau a wneir o dan y darpariaethau. Mae'r cymal yn awr yn darparu bod rhaid i'r is-ddeddfwriaeth honno a wneir oddi tani ddarparu fel y gall Gweinidogion Cymru neu berson a ddynodir ganddynt, megis Iechyd a Gofal Digidol Cymru, gasglu gwybodaeth, yn ddarostyngedig i eithriadau penodedig yn yr is-ddeddfwriaeth honno. Mae'r diwygiad yn sicrhau, pan fo'n briodol, fod data yn parhau i fod ar gael i Weinidogion Cymru eu defnyddio.

Yn olaf, yn ogystal â'r mesurau diogelu y cytunwyd arnynt ar wyneb y Bil fel y'i cyflwynwyd, mae'n ofynnol yn awr ymgynghori â Gweinidogion Cymru ar unrhyw reoliadau neu gyfarwyddiadau sy'n ymwneud â systemau gwybodaeth meddyginiaethau sy'n berthnasol i Gymru. Ceir Memorandwm Cyd-ddealltwriaeth – y bydd Llywodraeth y DU a'r Llywodraethau Datganoledig yn ei lunio ac yn cytuno arno ar y cyd – i gefnogi hyn. Rydym wedi egluro wrth Lywodraeth y DU fod angen llunio'r Memorandwm hwn cyn gynted â phosibl, a'r nod yw y bydd yn ei le cyn i'r darpariaethau ddod i rym.

Gyda'i gilydd, rwy'n fodlon bod y diwygiadau a wnaed i'r darpariaethau hyn yn mynd i'r afael â'n prif bryderon ac, o ganlyniad, gallaf yn awr gefnogi'r cymal hwn o'r Bil.

## **Argymhellion 2 a 3 - Cymalau 88-94 (Cymalau 86-92 gynt): Trosglwyddo swyddogaethau cyrff hyd braich**

### Argymhelliad 2

Dylai'r Gweinidog, cyn y cynhelir dadl y Senedd ar y cynnig cydsyniad perthnasol, ddarparu manylion pellach am y trafodaethau rhynglywodraethol a gafwyd ynghylch cymalau 86 i 92, a dylai gadarnhau a fydd y diwygiadau y mae wedi'u ceisio yn cael eu cyflwyno i'r Bil gan Lywodraeth y DU

### Ymateb:

Aed i'r afael â'm dau brif bryder yn y maes hwn.

Ar 24 Ionawr 2022, cafodd diwygiad ei gyflwyno gan Lywodraeth y DU sy'n darparu ar gyfer gofyniad statudol i gael cydsyniad, sy'n ei gwneud yn ofynnol i gael cydsyniad Gweinidogion Cymru cyn y gall yr Ysgrifennydd Gwladol wneud rheoliadau o dan gymalau 89 (cymal 87 gynt) (Pŵer i drosglwyddo swyddogaethau rhwng cyrff) neu gymal 90 (cymal 88 gynt) (Pŵer i ddarparu ar gyfer arfer swyddogaethau'r Ysgrifennydd Gwladol) pan fo'r rheoliadau hynny'n cynnwys darpariaeth a fyddai o fewn cymhwysedd deddfwriaethol y Senedd pe bai wedi'i chynnwys mewn Deddf gan y Senedd (ac nad yw ond yn gysylltiedig â darpariaeth, neu'n ganlyniadol i ddarpariaeth, a fyddai y tu allan i'r cymhwysedd deddfwriaethol hwnnw) neu sy'n addasu swyddogaethau Gweinidogion Cymru (hy addasu eu cymhwysedd gweithredol).

Mae rhagor o fanylion ynghylch y diwygiad hwn i'w gweld yn y Memorandwm Cydsyniad Deddfwriaethol Atodol (Memorandwm Rhif 3) a osodwyd gerbron y Senedd ar 28 Ionawr 2022.

O ran fy mhryderon ynghylch gallu'r Ysgrifennydd Gwladol i drosglwyddo eiddo, hawliau a rhwymedigaethau eraill oddi wrth Gyrff Hyd Braich i Weinidogion Cymru, Ymddiriedolaethau GIG Cymru ac Awdurdodau Iechyd Arbennig penodol i Gymru yng nghymal 92 (cymal 90 gynt), i ddatrys hyn, cyflwynodd Llywodraeth y DU hefyd, ar 24 Ionawr, ddiwygiadau sy'n dileu Gweinidogion Cymru, Ymddiriedolaethau GIG Cymru ac Awdurdodau Iechyd Arbennig penodol i Gymru o'r rhestr o "bersonau priodol" yn y cymal, gan fynd i'r afael yn llawn â'n pryderon yn y maes hwn felly.

Yn fy marn i, fel y nodir yn yr ymateb i Argymhelliad 8, isod, mae Llywodraeth y DU wedi mynd i'r afael â'm pryder ynghylch cymal 91, sy'n rhoi'r pŵer i'r Ysgrifennydd Gwladol, drwy reoliadau, wneud darpariaeth sy'n ganlyniadol i gymalau 88 neu 90 (cymalau 86 ac 88 gynt) o'r Bil.

### Argymhelliad 3

Dylai'r Gweinidog ofyn i'r Bil gael ei ddiwygio i fynd i'r afael â'i phryderon ynghylch cymal 87 fel na all yr Ysgrifennydd Gwladol ddefnyddio'r pwerau yn y cymal hwnnw i drosglwyddo a/neu ddirprwyo swyddogaethau mewn perthynas ag Awdurdodau Iechyd Arbennig lle cafodd y swyddogaethau hynny eu cyfarwyddo gan Weinidogion Cymru mewn perthynas â Chymru.

### Ymateb:

Fel y nodwyd yn fy ymateb i Argymhelliad 2, uchod, ar yr amod y caiff diwygiadau Llywodraeth y DU a osodwyd ar 24 Ionawr eu pasio, dim ond gyda chydsyniad Gweinidogion Cymru y gellir arfer y pŵer hwn, ac mae hyn yn mynd i'r afael yn llawn â'n pryderon yn y maes hwn felly.

## **Argymhellion 4 a 5 - Cymal 136 (Cymal 120 gynt): Trefniadau gofal iechyd rhyngwladol**

### Argymhelliad 4

Dylai'r Gweinidog, cyn y ddadl yn y Senedd ar y cynnig cydsyniad perthnasol, roi copi i'r Pwyllgor a holl Aelodau'r Senedd o'r Memorandwm Cyd-ddealltwriaeth terfynol sydd ar waith rhwng Llywodraeth Cymru a Llywodraeth y DU mewn perthynas â Deddf Gofal Iechyd (Trefniadau'r Ardal Economaidd Ewropeaidd a'r Swistir) 2019, a chadarnhau bod testun y Memorandwm Cyd-ddealltwriaeth yn adlewyrchu cwmpas terfynol, cyfyngedig y Bil fel y'i cytunwyd gan Senedd y DU.

### Ymateb:

Mae'n bleser gennyf amgáu'r Memorandwm Cyd-ddealltwriaeth ar gyfer y trefniadau gofal iechyd cilyddol gyda'r llythyr hwn i'w ystyried gan y Pwyllgor, y gallaf gadarnhau ei fod yn adlewyrchu darpariaethau'r Bil fel y'i diwygiwyd ar 23 Tachwedd 2021. Mae pob un o'r pedair gwlad wedi cytuno ar y Memorandwm Cyd-ddealltwriaeth. Bydd y Pwyllgor am nodi nad yw'r cysylltiadau ehangach mewn perthynas â'r trefniadau llywodraethiant newydd ar gyfer cysylltiadau rhynglywodraethol wedi'u cynnwys yn y Memorandwm Cyd-ddealltwriaeth hyd yma, ond maent yn cael eu hystyried. Bydd y Memorandwm Cyd-ddealltwriaeth yn cael ei ddiweddarau i adlewyrchu'r trefniadau newydd ar gyfer cysylltiadau rhynglywodraethol maes o law.

## Argymhelliad 5

Dylai'r Gweinidog ofyn i'r Bil gael ei ddiwygio i gynnwys prawf clir a chymesur ar wyneb y Bil ar gyfer yr hyn sy'n gymwys fel 'amgylchiad eithriadol' yng nghymal 120.

### Ymateb:

Ar hyn o bryd, mae adran 1 o Ddeddf Gofal Iechyd (Trefniadau'r Ardal Economaidd Ewropeaidd a'r Swistir) 2019 yn rhoi pŵer i'r Ysgrifennydd Gwladol wneud taliadau, a threfnu i daliadau gael eu gwneud, mewn perthynas â chost gofal iechyd a ddarperir yn un o wladwriaethau'r Ardal Economaidd Ewropeaidd neu'r Swistir.

Bydd cymal 136 (cymal 120 gynt) o'r Bil yn dileu'r pŵer yn adran 1 o Ddeddf Gofal Iechyd (Trefniadau'r Ardal Economaidd Ewropeaidd a'r Swistir) 2019 ac yn ei ddisodli â phwerau gwneud rheoliadau sy'n galluogi'r Ysgrifennydd Gwladol i wneud rheoliadau (a) er mwyn rhoi effaith i gytundeb gofal iechyd (gan gynnwys mewn perthynas â gwneud taliadau) rhwng y DU a naill ai gwlad neu diriogaeth y tu allan i'r DU neu sefydliad rhyngwladol, a (b) awdurdodi'r Ysgrifennydd Gwladol i wneud taliad mewn perthynas â gofal iechyd a ddarperir mewn modd heblaw am o dan gytundeb gofal iechyd, mewn gwlad neu diriogaeth y mae gan y DU gytundeb gofal iechyd cilyddol â hi, ond dim ond pan fo'r Ysgrifennydd Gwladol o'r farn y gellir cyfiawnhau'r taliad drwy amgylchiadau eithriadol.

Diben y pŵer sy'n galluogi'r Ysgrifennydd Gwladol i ariannu gofal iechyd y tu allan i gytundeb gofal iechyd rhyngwladol mewn amgylchiadau eithriadol yw cynorthwyo Llywodraeth y DU i gefnogi anghenion gofal iechyd pobl sy'n preswyllo ym Mhrydain pan fyddant dramor mewn amgylchiadau a allai fel arall ddisgyn, o fewn dim, y tu allan i gytundeb gofal iechyd cilyddol.

Yn y gorffennol, er enghraifft, mae Llywodraeth y DU wedi defnyddio pwerau presennol o dan Ddeddf Gofal Iechyd (Trefniadau'r Ardal Economaidd Ewropeaidd a'r Swistir) 2019 i ddarparu cymorth gofal iechyd ar gyfer argyfwng iechyd meddwl i blentyn dan oed yn yr UE pan fo'r Aelod-wladwriaeth wedi dweud nad oedd y driniaeth yn cael ei chynnwys o dan gynllun y Cerdyn Yswiriant Iechyd Ewropeaidd. Mae Llywodraeth y DU hefyd wedi ariannu triniaeth yn yr UE ar gyfer gefeilliaid sydd â haemangiomâu babandod a gafodd eu geni i rieni sy'n preswyllo yn y DU ond nad oeddent yn gallu teithio'n hawdd yn ôl i'r DU oherwydd cyfyngiadau teithio COVID-19 a'r risgiau a oedd yn gysylltiedig â theithio ar y pryd. Ni fyddent fel arall wedi bod o fewn cwmplas y darpariaethau sy'n gysylltiedig â thriniaeth wedi'i chynllunio yng nghytundebau gofal iechyd cilyddol yr UE oherwydd gallent fod wedi cael y driniaeth yn y DU heb oedi diangen pe baent wedi bod yn y DU ar y pryd.

Mae taliadau am ofal iechyd y tu allan i'r DU yn fater a gedwir yn ôl oherwydd eu bod yn ymwneud â llesiant pobl y tu allan i'r DU, ac nid ydynt yn cael unrhyw effaith o sylwedd ar y ddarpariaeth gofal iechyd ddomestig yn y DU, ac nid ydynt ychwaith yn gysylltiedig â'r ddarpariaeth honno. Pa un a fydd y DU yn penderfynu trefnu ac ariannu gofal iechyd i bobl y tu allan i'r DU ai peidio, ac i ba raddau – mater cysylltiadau rhyngwladol yw hwnnw.

Mae'n debygol mai'r amgylchiadau hynny pan fyddai gwrthod ariannu triniaeth gofal iechyd yn arwain at ganlyniadau llym, na ellir eu cyfiawnhau, i'r unigolyn, i'r graddau fel na fyddai gwrthod cais am gyllid yn ymateb cymesur, yw amgylchiadau eithriadol. Mae'n anorffod bod rhaid cydbwyso unrhyw fuddiannau cyhoeddus â buddiannau'r unigolyn dan sylw sy'n gwrthdaro â'i gilydd wrth benderfynu a ellir cyfiawnhau talu am driniaeth drwy amgylchiadau eithriadol. Byddai ceisio diffinio hyn ymhellach mewn deddfwriaeth sylfaenol drwy gyfeirio at faint neu'r math o ofal iechyd y gellir ei ariannu yn cyfyngu'n ormodol ar

allu'r Ysgrifennydd Gwladol i arfer y disgrisiwn hwn a byddai'n llesteirio'r gallu i gynorthwyo pobl sy'n preswyllo ym Mhrydain pan fydd arnynt angen fwyaf.

Yn fy marn i, felly, nid yw'n briodol cynnwys prawf clir a chymesur ar wyneb y Bil ar gyfer yr hyn a fyddai'n gymwys fel 'amgylchiad eithriadol' o safbwynt faint neu ba fath o ofal iechyd y gellir ei ariannu y tu allan i gytundeb gofal iechyd rhyngwladol oherwydd gallai hyn gael effaith andwyol ar ddarparu cymorth pan fo ei angen, neu gallai gyfyngu ar y cymorth y gellid ei ddarparu.

## **Argymhelliad 6 - Cymal 142 (Cymal 123 gynt): Rheoleiddio gofal iechyd a phroffesiynau cysylltiedig**

### Argymhelliad 6

Dylai'r Gweinidog, cyn y cynhelir dadl y Senedd ar y cynnig cydsyniad perthnasol, ddarparu manylion pellach am y trafodaethau rhynglywodraethol a gafwyd ynghylch cymal 123, a dylai gadarnhau a fydd y diwygiad y mae wedi ei geisio yn cael ei gyflwyno i'r Bil gan Lywodraeth y DU.

### Ymateb:

Gallaf gadarnhau bod y diwygiad a geisiwyd gennym wedi'i gyflawni a bod y Bil wedi'i ddiwygio er mwyn ei gwneud yn ofynnol i gael cydsyniad Gweinidogion Cymru ar gyfer Gorchymyn yn y Cyfrin Gyngor a wneir o dan adran 60 o Ddeddf Iechyd 1999, sy'n gwneud darpariaeth sydd o fewn cymhwysedd deddfwriaethol y Senedd ac sy'n dod â grŵp o weithwyr nad ydynt yn weithwyr proffesiynol, ond sy'n ymwneud ag iechyd corfforol neu iechyd meddwl unigolion, o dan drefniadau rheoleiddio.

Mae rhagor o fanylion ynghylch y diwygiad i'w gweld yn y Memorandwm Cydsyniad Deddfwriaethol Atodol a osodwyd gerbron y Senedd ar 17 Rhagfyr 2021.

## **Argymhelliad 7 - Cymal 144 ac Atodlen 17 (Cymal 125 ac Atodlen 16 gynt): Hysbysebu bwyd a diod llai iachus**

### Argymhelliad 7

Dylai'r Gweinidog, cyn y cynhelir dadl y Senedd ar y cynnig cydsyniad perthnasol, ddarparu manylion pellach am y trafodaethau rhynglywodraethol a gafwyd ynghylch cymal 125 ac Atodlen 16 i'r Bil.

### Ymateb:

Nodais yn fy llythyr i'r Pwyllgor dyddiedig 28 Hydref 2021, er bod cynnwys y cymalau sy'n ymwneud â chyfyngiadau ar hysbysebu bwyd nad yw'n iach ar sail pedair gwlad, o ran ei sylwedd, yn cael ei groesawu, fod pŵer canlyniadol wedi'i gynnwys sy'n galluogi'r Ysgrifennydd Gwladol i ddiwygio deddfwriaeth Gymreig.

Dylid nodi bod hwn yn faes o'r Bil nad yw Llywodraeth y DU yn derbyn ei fod wedi'i ddatganoli ac felly nid yw'n cytuno y dylai fod yn ddarostyngedig i ofyniad am gydsyniad deddfwriaethol y Senedd.

Fodd bynnag, fel y nodir yn yr ymateb i Argymhelliad 8, isod, ar sail y sicrwydd a roddwyd gan Lywodraeth y DU ynghylch y defnydd posibl o'r pwerau, rydym yn derbyn y diwygiadau canlyniadol a allai godi o gymal 144 (cymal 125 gynt) fel risg gyfansoddiadol fach a derbyniol.

## **Argymhelliad 8 - Cymalau 149, 144 a 91 (cymalau 89, 125 a 130 gynt): Diwygiadau canlyniadol i ddeddfwriaeth y Senedd**

### Argymhelliad 8

Dylai'r Gweinidog geisio gwelliant i'r Bil i'r perwyl na all Gweinidogion y DU ddefnyddio'r pwerau yn y Bil i wneud rheoliadau sy'n diwygio Deddf Llywodraeth Cymru 2006.

### Ymateb:

Mae'r cymalau hyn yn rhoi pŵer i'r Ysgrifennydd Gwladol wneud, drwy reoliadau, ddarpariaeth sy'n ganlyniadol i'r Bil. Mae hyn yn cynnwys darpariaeth sy'n diwygio, yn diddymu, yn dirymu neu'n addasu fel arall unrhyw ddarpariaeth a wneir gan, neu o dan, Ddeddf neu Fesur gan y Senedd.

Fel y nodir yn y Memorandwm Cydsyniad Deddfwriaethol Atodol (Memorandwm Rhif 3) a osodwyd ar 28 Ionawr 2022, rwyf i a'm swyddogion wedi cyfarfod ag Edward Argar AS, y Gweinidog Gwladol dros lechyd, a'i swyddogion ar sawl achlysur i drafod y darpariaethau hyn. Mae Llywodraeth y DU o'r farn bod y rhain yn gymalau safonol ac mae Cymru, yn yr un modd, yn cymryd pwerau mewn Deddfau gan y Senedd i wneud diwygiadau canlyniadol i ddeddfwriaeth Llywodraeth y DU.

Mae swyddogion Llywodraeth y DU wedi darparu enghreifftiau o sut y gellir defnyddio'r pwerau hyn. Byddai'r diwygiadau yn debygol o fod yn rhai mân eu natur, er enghraifft newid enw sefydliad yn Lloegr y cyfeirir ato mewn deddfwriaeth gan y Senedd pan fo swyddogaethau wedi cael eu trosglwyddo. Mae'r Gweinidog Gwladol dros lechyd hefyd wedi ymrwymo'n ysgrifenedig i wneud datganiad gerbron y Blwch Dogfennau mewn perthynas â chymalau 91 a 149, ar sut y gellid defnyddio'r pwerau hyn. (Fel y dywedwyd mewn ymateb i Argymhelliad 7 uchod, nid yw Llywodraeth y DU wedi nodi bod ei bod yn ofynnol i gymal 144 gael cydsyniad deddfwriaethol y Senedd ac felly ni fydd yn ei gynnwys yn y datganiad gerbron y Blwch Dogfennau).

Rydym wedi cytuno ar eiriad y datganiad gerbron y Blwch Dogfennau gyda Llywodraeth y DU ac mae Llywodraeth y DU wedi ymrwymo i wneud y datganiad cyn y ddadl ar y Cynnig Cydsyniad Deddfwriaethol yn y Senedd a fydd yn cael ei chynnal ar 15 Chwefror.

Ar sail y datganiad sy'n cael ei wneud, ac yng ngoleuni'r holl sicrwydd a roddwyd gan Lywodraeth y DU, rwy'n ystyried bod y risg a gyflwynir gan y darpariaethau yn awr yn dderbyniol.

Hyderaf y bydd yr ymateb hwn o gymorth wrth i'r Pwyllgor graffu ar y Memoranda Cydsyniad Deddfwriaethol ar gyfer y Bil.

Rwy'n anfon copi o'r llythyr hwn at Russell George AS, Cadeirydd y Pwyllgor lechyd a Gofal Cymdeithasol.

Yn gywir



**Eluned Morgan AS/MS**

Y Gweinidog lechyd 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**

**CONTENTS**

- A. INTRODUCTION**
  - 1. Overview and Scope
  - 2. Overarching Principles
- B. CONSULTATION PROCESS – POLICY AND AGREEMENTS**
  - 3. Policy Mandate and Formation
  - 4. Negotiations and Drafting of International Agreements
  - 5. Ministerial Engagement
  - 6. Dispute Resolution
  - 7. Confidentiality
- C. CONSULTATION PROCESS - IMPLEMENTATION AND REVIEW**
  - 8. Regulations under Healthcare (International Arrangements) Act 2019
  - 9. Operational Implementation
  - 10. Review
- D. DATA SHARING**
- E. SIGNATORIES**
- ANNEX A**

**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

