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Annwyl Huw

Diolch am eich llythyr dyddiedig 15 Mai ynghylch Rheoliadau Gofal Iechyd (Trefniadau Rhyngwladol) (Ymadael â'r UE) 2023 ("Rheoliadau HIA"). Rwyf wedi ateb eich cwestiynau am Reoliadau HIA isod.

Cwestiwn 1

Yn y llythyr rydych yn nodi y bydd y Rheoliadau HIA "yn cael eu gwneud drwy arfer pwerau a roddir i'r Ysgrifennydd Gwladol gan Ddeddf Gofal Iechyd (Trefniadau Rhyngwladol) 2019 ("y Ddeddf") (a arferai gael ei galw yn Ddeddf Gofal Iechyd (Trefniadau'r Ardal Economaidd Ewropeaidd a'r Swistir) 2019 ond sy'n cael ei hailenwi gan adran 162 o Ddeddf Iechyd a Gofal 2022). Pan ddaw adran 162 i rym, bydd yn peri i'r prif bŵer galluogi ar gyfer y Rheoliadau HIA gychwyn". Pryd y bydd adran 162 o Ddeddf Iechyd a Gofal 2022 (Deddf 2022) yn dod i rym?

Mae fy swyddogion yn disgwyl y caiff ei chychwyn yn yr haf, ar sail yr wybodaeth a ddarparwyd gan eu swyddogion cyfatebol yn Llywodraeth y DU.

Cwestiwn 2

Yn eich llythyr rydych yn nodi "Mae'r Rheoliadau HIA yn debyg i'r Rheoliadau HEEASA i raddau helaeth, ond maent yn ehangu cwmpas y fframwaith cyfreithiol i gynnwys cytundebau gofal iechyd rhwng Llywodraeth y DU a gwledydd Gweddill y Byd." Rydych hefyd yn nodi "Mae'r ddarpariaeth deddfwriaethol amnewid a wneir gan y Rheoliadau HIA mewn perthynas â chyfundrefn y DU ar gyfer gofal iechyd cilyddol yn cadw'r status quo yn fras o dan y Rheoliadau HEEASA cyfredol." Byddem yn ddiolchgar i gael rhagor o eglurder ar y gwahaniaethau penodol rhwng y Rheoliadau HIA a Rheoliadau HEEASA a'r hyn a olygir gan yr ymadrodd "yn cadw'r status quo yn fras".

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

Mae Rheoliadau Gofal Iechyd (Trefniadau'r Ardal Economaidd Ewropeaidd a'r Swistir) (Ymadael â'r UE) 2019 ("Rheoliadau HEEASA") yn gwneud y canlynol:

- rhoi dyletswydd i Awdurdod Gwasanaethau Busnes GIG y DU, yn ddarostyngedig i gyfarwyddiadau a roddir gan yr Ysgrifennydd Gwladol, i wneud taliadau ar sail y DU gyfan o dan adran 1 o Ddeddf Gofal Iechyd (Trefniadau'r Ardal Economaidd Ewropeaidd a'r Swistir) 2019 ("Deddf 2019") (sy'n galluogi'r Ysgrifennydd Gwladol i wneud taliadau, neu i drefnu i daliadau gael eu gwneud, mewn cysylltiad â chostau gofal iechyd a ddarperir mewn un o wladwriaethau'r Ardal Economaidd Ewropeaidd neu'r Swistir), ac i helpu'r Ysgrifennydd Gwladol i arfer swyddogaethau'r Ysgrifennydd Gwladol mewn cysylltiad â gwneud taliadau o'r fath, gan roi effaith i gytundebau a threfniadau gofal iechyd a darpariaeth gofal iechyd mewn aelod-wladwriaethau;
- rhoi swyddogaethau i Awdurdod Gwasanaethau Busnes y GIG a'r Ysgrifennydd Gwladol i roi effaith i rwymedigaethau ac ymrwymadau'r DU o dan gytundebau neu drefniadau gofal iechyd;
- gosod swyddogaethau gwybodaeth a chyngor ar Awdurdod Gwasanaethau Busnes y GIG (h.y. i sefydlu a chynnal gwasanaeth gwybodaeth a chyngor i'r cyhoedd);
- rhoi swyddogaethau triniaeth wedi'i chynllunio S2 i Fyrddau Iechyd Lleol Cymru, NHS England a Byrddau Iechyd yr Alban (h.y. i wneud penderfyniadau clinigol ynghylch ceisiadau yn unol â chytundebau a threfniadau gofal iechyd rhyngwladol);
- darparu i Weinidogion y Llywodraethau Datganoledig a'r Ysgrifennydd Gwladol, ar y cyd â'r byrddau iechyd perthnasol, gael penderfynu ynghylch ceisiadau am driniaeth (wedi'i chynllunio) S2 y GIG.

Mae Rheoliadau HIA yn 'cadw'r status quo yn fras' am fod rolau'r Ysgrifennydd Gwladol, Awdurdod Gwasanaethau Busnes y GIG a'r byrddau iechyd perthnasol (e.e. Byrddau Iechyd Lleol Cymru mewn perthynas â Chymru) o fewn y fframwaith cyfreithiol yn aros yr un peth i bob pwrpas.

Dileodd adran 162 o Ddeddf Iechyd a Gofal 2022 ("Deddf 2022") bŵer ehangach yr Ysgrifennydd Gwladol i wneud taliadau gofal iechyd yn adran 1 o Ddeddf 2019 a'r pŵer i wneud rheoliadau mewn perthynas â gofal iechyd a threfniadau gofal iechyd yn adran 2 o Ddeddf 2019. Cafodd y pwerau hynny eu creu er mwyn helpu pobl i fanteisio ar ofal iechyd yn yr Ardal Economaidd Ewropeaidd a'r Swistir pe bai'r DU yn ymadael â'r Undeb Ewropeaidd heb gytundeb ac felly ni fyddai angen mesurau o'r fath mwyach. Yn adran 162, cafodd y pwerau blaenorol eu disodli gan bŵer i wneud rheoliadau yn ôl disgrisiwn ynghylch cytundebau a thaliadau gofal iechyd. O ganlyniad i hynny, mae Rheoliadau HIA yn caniatáu i'r Ysgrifennydd Gwladol, ar sail y DU gyfan, wneud taliadau a threfnu i daliadau gael eu gwneud mewn cysylltiad â gofal iechyd a ddarperir mewn gwlad a restrir o dan gytundeb gofal iechyd, ac i wneud taliadau (ac eithrio o dan gytundeb gofal iechyd) mewn cysylltiad â gofal iechyd a ddarperir mewn gwlad a restrir pan fo'r Ysgrifennydd Gwladol yn ystyried bod amgylchiadau eithriadol yn cyfiawnhau'r taliad (gyda modd i Awdurdod Gwasanaethau Busnes y GIG, Byrddau Iechyd Lleol Cymru, NHS England a Byrddau Iechyd Lleol yr Alban wneud atgyfeiriadau ar gyfer ceisiadau neu hawliadau am daliadau o'r fath).

O dan Rheoliadau HIA, bydd yn ofynnol o hyd i Awdurdod Gwasanaethau Busnes y GIG roi effaith i rwymedigaethau ac ymrwymadau'r DU o dan gytundebau gofal iechyd perthnasol, i helpu'r Ysgrifennydd Gwladol i arfer ei swyddogaethau mewn perthynas â chytundebau gofal iechyd perthnasol a darpariaeth gofal iechyd mewn gwledydd a restrir ac i sefydlu a chynnal gwasanaeth gwybodaeth a chyngor i'r cyhoedd. Mae hefyd yn ofynnol o hyd i fyrddau iechyd perthnasol (e.e. Byrddau Iechyd Lleol Cymru mewn perthynas â Chymru) wneud penderfyniadau clinigol ynghylch ceisiadau am driniaeth wedi'i chynllunio S2, yn unol â'r cytundebau gofal iechyd perthnasol.

At hynny, ynghyd â nifer o newidiadau technegol, mae Rheoliadau HIA hefyd yn gwneud y canlynol:

- rhestru gwledydd sy'n rhan o gytundebau gofal iechyd rhyngwladol â'r DU (roedd Rheoliadau HEEASA, ar y llaw arall, yn ei gwneud yn ofynnol i'r Ysgrifennydd Gwladol gyhoeddi a chynnal rhestr ar wahân o gytundebau gofal iechyd rhyngwladol);
- yn ei gwneud yn ofynnol i'r Ysgrifennydd Gwladol, Awdurdod Gwasanaethau Busnes y GIG, Byrddau Iechyd Lleol Cymru, NHS England a Byrddau Iechyd yr Alban bennu a chyhoeddi gweithdrefnau ar gyfer penderfynu ynghylch ceisiadau a hawliadau sydd o fewn eu cylch gwaith, y mae'n rhaid iddynt gynnwys darpariaeth ar gyfer proses adolygu.

Nid yw Rheoliadau HIA yn dwyn ymlaen y pŵer yn HEEASA sy'n caniatáu i Weinidogion y Llywodraethau Datganoledig a'r Ysgrifennydd Gwladol, ar y cyd â'r byrddau iechyd perthnasol, benderfynu ynghylch ceisiadau am driniaeth (wedi'i chynllunio) S2 y GIG. Fodd bynnag, nid yw'r pŵer hwn yn Rheoliadau HEEASA erioed wedi cael ei ddefnyddio yng Nghymru, ac nid oes unrhyw amgylchiadau y gellir eu rhagweld pan fyddai Gweinidogion Cymru yn dymuno penderfynu ynghylch cais am driniaeth (wedi'i chynllunio) S2, gan fod ceisiadau o'r fath yn cael eu hasesu'n glinigol gan y Byrddau Iechyd Lleol. Nid oes gan Lywodraeth Cymru yr arbenigedd clinigol sy'n ofynnol i wneud penderfyniadau o'r fath ac i roi'r cyngor perthnasol i'r Gweinidogion yn hyn o beth felly.

Am fod adran 162 o Ddeddf 2022 hefyd yn ei gwneud yn bosibl i reoliadau gael eu gwneud yn y maes hwn sy'n rhoi cytundebau cilyddol cynhwysfawr ar waith â gwledydd y tu allan i'r Ardal Economaidd Ewropeaidd a'r Swistir, mae Rheoliadau HIA yn gymwys i gytundebau gofal iechyd perthnasol a restrir â gwledydd Gweddill y Byd.

Cwestiwn 3

Byddwch yn ymwybodol, yn ein hadroddiad ar Femorandwm Cydsyniad Deddfwriaethol Llywodraeth Cymru ar y Bil Iechyd a Gofal (adroddiad Rhagfyr 2021) ac yn ein hadroddiad dilynol ar Femoranda Cydsyniad Deddfwriaethol Atodol Llywodraeth Cymru (Memorandwm Rhif 2 a Memorandwm Rhif 3) ar y Bil Iechyd a Gofal (adroddiad Chwefror 2022), ein bod yn mynegi pryderon am yr hyn a ddaeth yn adran 162 o Ddeddf 2022, ehangder y pwerau dirprwyedig y mae'n eu darparu i Weinidogion, a'r canlyniadau y gallai rheoliadau o'r fath eu cael ar gyrff y GIG yng Nghymru.

Mae Casgliad 6 yn ein hadroddiad Chwefror 2022 yn dweud "Dylai Gweinidogion Cymru wneud unrhyw reoliadau angenrheidiol mewn meysydd datganoledig at ddiben dod â chytundebau gofal iechyd rhyngwladol i rym. Pan na fyddant yn gwneud hynny, a bod y pŵer i roi swyddogaethau perthnasol i'r Byrddau Iechyd Lleol ynghylch cytundebau gofal iechyd yn cael ei arfer yn lle hynny gan yr Ysgrifennydd Gwladol, rhaid i Weinidogion Cymru roi manylion ac esboniad llawn i'r Senedd cyn i reoliadau o'r fath gael eu gwneud gan yr Ysgrifennydd Gwladol."

Rydym yn cydnabod bod eich llythyr dyddiedig 25 Ebrill yn hysbysu'r Senedd am y bwriad i wneud y Rheoliadau HIA gan yr Ysgrifennydd Gwladol. Byddem yn croesawu cadarnhad ac eglurder ynghylch sut yr ymgynghorwyd â Byrddau Iechyd Lleol Cymru ar y Rheoliadau HIA.

Mae fy swyddogion wedi bod yn rhoi'r wybodaeth ddiweddaraf i'r Byrddau Iechyd Lleol ar gynnydd Rheoliadau HIA, ac maent wedi ymgynghori'n benodol ar y rhan o Reoliadau HIA sy'n gosod dyletswydd newydd arnynt (h.y. y gofyniad i fyrddau iechyd lleol bennu a chyhoeddi gweithdrefnau ar gyfer penderfynu ynghylch ceisiadau S2, gan gynnwys darpariaeth ar gyfer proses adolygu). Mae Llywodraeth y DU hefyd wedi ymgynghori â'r Byrddau Iechyd Lleol ar y broses a'r canllawiau ar gyfer gwneud cais i'r Ysgrifennydd

Gwladol am daliadau gofal iechyd o dan amgylchiadau eithriadol, gan fod Bwrdd Iechyd Lleol y claf yn gallu gwneud cais amdanynt ar ei ran.

Cwestiwn 4

Yn eich llythyr rydych chi'n nodi "Rhestrir gwledydd a gwmpesir gan Gytundebau Gofal Iechyd Rhyngwladol mewn Atodlen i'r Rheoliadau HIA. O ystyried bod Llywodraeth y DU am geisio cytundebau â nifer o wledydd yn y blynyddoedd sydd i ddod, a bydd angen diwygio'r Atodlen gan ddefnyddio'r weithdrefn gadarnhaol bob tro y bydd gwledydd yn cael eu rhestru, rwy'n ystyried ei fod yn fwy ymarferol ac effeithlon bod Llywodraeth y DU yn gwneud y gwaith hwn ar ein rhan." Fel yr amlygwyd yn y cwestiwn blaenorol, mae casgliad 6 yn ein hadroddiad Chwefror 2022 yn argymhell y dylai Llywodraeth Cymru wneud unrhyw reoliadau angenrheidiol mewn meysydd datganoledig at ddiben dod â chytundebau gofal iechyd rhyngwladol i rym.

a) A allwch egluro pam eich bod yn ystyried ei bod yn "fwy ymarferol ac effeithlon bod Llywodraeth y DU yn gwneud y gwaith hwn ar [eich] rhan".

Bob tro y mae Llywodraeth y DU yn ymrwmo i gytundeb gofal iechyd newydd â gwlad neu diriogaeth, bydd angen diwygio Rheoliadau HIA er mwyn ychwanegu'r wlad honno neu'r diriogaeth honno i'r Atodlen ar sail y DU gyfan, er mwyn rhoi effaith i'r cytundeb a'i weithredu ledled y DU. O ystyried bod Llywodraeth y DU yn bwriadu ceisio cytundebau â nifer o wledydd yn y blynyddoedd sydd i ddod, gallai fod angen gwneud cyfres barhaus o ddiwygiadau i'r Atodlen. Bydd yn ofynnol i Lywodraeth y DU ddiwygio'r Atodlen bob tro y mae'n ymrwmo i gytundeb gofal iechyd newydd, o leiaf o ran Lloegr. Am fod ganddi'r cymhwysedd hefyd i ddiwygio'r Atodlen ar sail y DU gyfan, mae'n ymarferol ac yn effeithlon iddi gymhwyso unrhyw ddiwygiad o'r fath i Gymru, o ystyried y byddai angen diwygiad cyfatebol o ran Cymru beth bynnag.

At hynny, fel y nodir isod, mae'n debygol mai ychydig iawn o effaith fydd rhestru cytundebau o'r fath yn Rheoliadau HIA yn ei chael ar y Byrddau Iechyd Lleol. Felly, nid deddfu ar wahân i Gymru pan fydd angen rhestru cytundeb newydd fyddai'r ffordd fwyaf priodol o roi effaith i'r newidiadau sydd eu hangen yn fy marn i, ac ni fyddai'n ddefnydd doeth o adnoddau Llywodraeth Cymru o ystyried blaenoriaethau pwysig eraill.

b) Allwch chi gadarnhau, pan fydd y pŵer i roi swyddogaethau perthnasol i'r Byrddau Iechyd Lleol ynghylch cytundebau gofal iechyd yn cael ei arfer gan yr Ysgrifennydd Gwladol yn y dyfodol, y bydd Gweinidogion Cymru yn rhoi manylion ac esboniad llawn i'r Senedd cyn i reoliadau o'r fath gael eu gwneud.

Gallaf gadarnhau y bydd Llywodraeth Cymru yn parhau i roi gwybod i'r Senedd pan fo Llywodraeth y DU yn arfer pŵer deddfwriaethol dirprwyedig mewn maes datganoledig o ran Cymru, gan egluro'r rhesymeg dros hyn.

c) Pa asesiadau fydd yn cael eu gwneud gan Lywodraeth Cymru o'r goblygiadau i Fyrddau Iechyd Lleol Cymru cyn rhoi unrhyw gydsyniad i Lywodraeth y DU wneud rheoliadau pellach sy'n ychwanegu gwledydd at yr Atodlen?

Nid yw'n ofynnol yn statudol i Lywodraeth y DU geisio cydsyniad Gweinidogion Cymru mewn cysylltiad â rheoliadau pellach sy'n ychwanegu rhagor o wledydd i'r Atodlen. Yn sgil cychwyn adran 162 o Ddeddf Iechyd a Gofal 2022 ac ar ôl i Reoliadau HIA ddod i rym, bydd adran 5 o Ddeddf Gofal Iechyd (Cytundebau Rhyngwladol) 2019 (a oedd yn dwyn y teitl Deddf Gofal Iechyd (Trefniadau'r Ardal Economaidd Ewropeaidd a'r Swistir) 2019 gynt) yn cynnwys gofyniad statudol i'r Ysgrifennydd Gwladol ymgynghori â Gweinidogion Cymru cyn gwneud rheoliadau sy'n cynnwys unrhyw ddarpariaeth sydd o fewn cymhwysedd

deddfwriaethol y Senedd. Dylid gwneud hyn o dan delerau'r Memorandwm Cyd-ddealltwriaeth Rhynglywodraethol mewn perthynas â'r Broses Ymgynghori ar gyfer Cytundebau Gofal Iechyd Rhyngwladol a'u Rheoliadau Gweithredu (sydd wedi ei amgáu gyda'r llythyr hwn – ar gael yn Saesneg yn unig).

Ychydig iawn o effaith y mae rhestru cytundebau pellach yn yr Atodlen i Reoliadau 2023 yn debygol o'i chael ar Fyrddau Iechyd Lleol, gan mai'r unig ddyletswyddau a roddir ar Fyrddau Iechyd Lleol gan Reoliadau HIA yw'r rheini sy'n ymwneud â thriniaeth wedi'i chynllunio S2. Fodd bynnag, caiff yr effeithiau hyn eu hystyried fel rhan o waith Llywodraeth Cymru i edrych ar effeithiau pob cytundeb unigol.

Nid yw'r rhan fwyaf o gytundebau gofal iechyd yn darparu ar gyfer trigolion y DU sy'n ceisio gofal iechyd wedi'i gynllunio dramor, a disgwylir y bydd hyn yn parhau mewn cytundebau yn y dyfodol. Nifer isel o drigolion Cymru sy'n ceisio gofal iechyd wedi'i gynllunio yn yr Undeb Ewropeaidd neu'r Swistir (sef yr unig gytundebu sy'n darparu ar gyfer hyn ar hyn o bryd). Mae'r DU wrthi ar hyn o bryd yn negodi Confensiwn Nawdd Cymdeithasol â'r Ardal Economaidd Ewropeaidd/ Gwladwriaethau'r Gymdeithas Fasnach Rydd Ewropeaidd, sef Lichtenstein, Gwlad yr Iâ a Norwy, sy'n debygol o gynnwys darpariaeth ar gyfer gofal iechyd wedi'i gynllunio. Fodd bynnag, ni ddisgwylir y byddai hyn yn cynyddu'n sylweddol nifer y cleifion o Gymru sy'n ceisio triniaeth wedi'i chynllunio dramor. At hynny, Llywodraeth y DU sy'n talu costau'r driniaeth ei hun ar gyfer cleifion o Gymru (heblaw'r costau hynny y mae rhaid i'r claf eu talu).

Dylid nodi bod cytundebau rhwng y DU a gwledydd eraill yn gosod rhwymedigaeth ar y DU yn ei chyfanrwydd, a'i bod yn ofynnol i Gymru eu rhoi ar waith a'u parchu. Felly, yn ymarferol, byddai rhaid i'r Byrddau Iechyd Lleol ymgymryd â dyletswydd debyg mewn cysylltiad â cheisiadau am driniaeth wedi'i chynllunio S2, p'un a yw cytundebau newydd wedi eu rhestru yn yr Atodlen i Reoliadau HIA ai peidio.

d) A allwch gadarnhau a ydych yn ymwybodol o unrhyw gytundebau gofal iechyd rhyngwladol sydd ar ddod.

Gallaf gadarnhau bod Confensiwn Nawdd Cymdeithasol, gan gynnwys elfennau o ofal iechyd cilyddol, wrthi'n cael ei negodi ar hyn o bryd â'r Ardal Economaidd Ewropeaidd/ Gwladwriaethau'r Gymdeithas Fasnach Rydd Ewropeaidd, sef Lichtenstein, Gwlad yr Iâ a Norwy (gyda Chonfensiwn Nawdd Cymdeithasol â'r Swistir wedi cael ei lofnodi y llynedd).

Gallaf hefyd gadarnhau bod Llywodraeth y DU wrthi'n datblygu cytundebau newydd neu ddiwygiedig â nifer o Dirioogaethau Tramor y DU a chyda Jersey ac Ynys Manaw.

e) Sut mae Llywodraeth Cymru a Byrddau Iechyd Lleol Cymru yn cael eu cynnwys yn y trafodaethau, neu yr ymgynghorir yn ddigonol â hwy, ynghylch cytundebau parhaus â gwledydd eraill ac yn y dyfodol?

Mae fy swyddogion yn cyfarfod yn rheolaidd â swyddogion y DU o dan delerau'r Memorandwm Cyd-ddealltwriaeth Rhynglywodraethol, ac yn cyfrannu at y gwaith o lunio cytundebau a rennir gan Lywodraeth y DU fel sy'n briodol.

Nid yw'n ofynnol o dan y Memorandwm Cyd-ddealltwriaeth Rhynglywodraethol i Lywodraeth y DU ymgynghori â'r byrddau iechyd lleol ar drefniadau gofal iechyd rhyngwladol. Fodd bynnag, mae'r byrddau iechyd lleol yn ymwybodol o'r gwaith sy'n mynd rhagddo gan Lywodraeth y DU yn y maes hwn, ac maent yn cyfarfod â'm swyddogion yn rheolaidd i drafod materion megis ymwelwyr tramor a gofal iechyd wedi'i gynllunio.

f) A allwch gadarnhau a yw'r Rheoliadau hyn yn cael eu cymryd drwy'r prosesau a amlinellir yn y Memorandwm Cyd-ddealltwriaeth Rhynglywodraethol mewn perthynas â'r Broses Ymgynghori ar gyfer Cytundebau Gofal Iechyd Rhyngwladol a'u Gweithredu (y gwnaed fersiwn ohonynt ar gael i ni ym mis Chwefror 2022).

Gallaf gadarnhau bod y broses a nodir yn adran 8 ("Rheoliadau o dan Ddeddf Gofal Iechyd (Cytundebau Rhyngwladol) 2019") o'r Memorandwm Cyd-ddealltwriaeth Rhynglywodraethol wedi cael ei dilyn wrth lunio Rheoliadau HIA.

Cwestiwn 5

Yn eich llythyr rydych yn nodi "Mae'r ddarpariaeth ddeddfwriaethol amnewid a wneir gan y Rheoliadau HIA mewn perthynas â chyfundrefn y DU ar gyfer gofal iechyd cilyddol yn cadw'r status quo yn fras o dan y Rheoliadau HEEASA cyfredol. Golyga hyn y byddai'r ddarpariaeth y byddai'r Ysgrifennydd Gwladol yn ei gwneud yn y Rheoliadau HIA mewn perthynas â Chymru ac mewn meysydd datganoledig yn cyfateb i'r ddarpariaeth y byddem ninnau yn ei gwneud mewn rheoliadau Cymru yn unig. Felly, ni fyddai'n niweidiol i'r safbwynt polisi yn y maes hwn pe bai Llywodraeth y DU yn gwneud y ddarpariaeth hon i Gymru. Nid yw'r dull gweithredu hwn ychwaith yn atal Gweinidogion Cymru rhag gwneud rheoliadau i Gymru yn unig o dan adran 2A o'r Ddeddf yn y dyfodol." Byddem yn croesawu eglurhad ac eglurder pellach ar eich datganiad sy'n nodi "ni fyddai'n niweidiol i'r safbwynt polisi yn y maes hwn pe bai Llywodraeth y DU yn gwneud y ddarpariaeth hon i Gymru".

Mae ein safbwynt polisi yn hyn o beth yr un peth â safbwynt Llywodraeth y DU ar hyn o bryd, ac nid wyf yn rhagweld y bydd y sefyllfa hon yn newid. Felly, mae darpariaethau Rheoliadau HIA yn gydnaws â'n polisi ni. Fel y nodwyd uchod, pe bai ein polisiau yn y maes hwn yn gwahanu oddi wrth ei gilydd yn y dyfodol, mae'r pŵer gennym o dan adran 2A o Ddeddf Gofal Iechyd (Trefniadau Rhyngwladol) 2019 i wneud ein rheoliadau ein hunain er mwyn gweithredu newidiadau penodol yng Nghymru, ar yr amod bod y newidiadau hyn o fewn cymhwysedd datganoledig, y mae ei gwmpas wedi ei ragnodi gan adran 2A(2) a (4)(b) o'r Ddeddf. Felly, ni fyddai'n niweidiol i bolisiau presennol Cymru na pholisiau'r dyfodol yn y maes hwn pe bai Llywodraeth y DU yn gwneud y ddarpariaeth hon i Gymru.

Hyderaf fod hyn yn ateb eich cwestiynau.

Mae copi o'r llythyr hwn wedi cael ei anfon at Russel George AS, Cadeirydd y Pwyllgor Iechyd a Gofal Cymdeithasol.

Yn gywir

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



