

EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CROSS-BORDER HEALTHCARE AND MISCELLANEOUS AMENDMENTS ETC) (EU EXIT) REGULATIONS 2019

2019 No. [XXXX]

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (DHSC) and is laid before Parliament by Act.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

- 2.1 This instrument remedies deficiencies in retained EU law relating to cross-border healthcare, which would arise from the withdrawal of the United Kingdom (UK) from the European Union (EU) in the event of no deal. The purpose of this instrument is to ensure that there will continue to be a functioning statute book on exit day and an effective mechanism to maintain cross-border healthcare arrangements in appropriate circumstances if the UK leaves the EU without a deal.

Explanations

What did any relevant EU law do before exit day?

- 2.2 Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (the Directive) came into force on 24 April 2011 with a transposition deadline of 25 October 2013. It clarified patients' rights to obtain qualifying healthcare in another European Economic Area (EEA) Member State and to receive reimbursement from their home healthcare system.
- 2.3 Reimbursement can be capped at the cost of state-provided treatment in a patient's home healthcare system. Eligible patients can receive reimbursement for qualifying private or state-provided treatments. The obligation to reimburse is limited to treatment which is the same as, or equivalent, to a treatment that would be made available to the person in their home healthcare system i.e. the NHS in relation to the UK. However, it provides a broader discretion for relevant UK authorities to pre-authorise treatments which may not be available in the UK.
- 2.4 The 'Directive rights' are separate from reciprocal healthcare arrangements under the social security coordination regulations (Regulations 883/2004 and 987/2009). Reimbursement rights under the Directive relate to the fundamental EU principle of the freedom to provide and avail of services, whereas the rights under the social security coordination regulations relate to the free movement of people. Payments for reciprocal healthcare under the social security coordination regulations are normally made state-to-state, whereas reimbursements under the 'directive route' are made to the individual.
- 2.5 In 2013, the UK Government and Devolved Administrations transposed the Directive into domestic legislation. The National Health Service (Cross-Border Healthcare)

Regulations 2013 implemented the majority of the Directive's provisions in England and Wales. Those implementing regulations made amendments to National Health Service Act 2006 and the National Health Service (Wales) Act 2006, as well as secondary legislation. Scotland and Northern Ireland each made equivalent implementing regulations. Gibraltar also made its own arrangements to transpose the Directive.

- 2.6 Commission Implementing Decisions 2011/890/EU and 2013/329/EU provide the rules for the establishment, management and functioning of the networks of national authorities or bodies responsible for eHealth and health technology assessment.

Why is it being changed?

- 2.7 As a responsible government, the UK Government will continue to proportionately prepare for all scenarios, including the outcome that we leave the EU without any deal in March 2019. This Statutory Instrument is intended to support other preparations the UK Government is making with regard to access to healthcare abroad.
- 2.8 Intervention is required to provide a suitable legislative framework for the Directive's arrangements after we leave the EU in a no deal scenario. This instrument is intended to remedy deficiencies in retained EU law relating to the Directive in the event that the UK leaves the EU without a deal.
- 2.9 This Statutory Instrument provides a mechanism for ensuring there is no interruption to healthcare arrangements for people accessing healthcare through the Directive after exit day in those Member States that agree to maintain the current arrangements in place with the UK for a transitional period until 31 December 2020. The arrangements would not apply to Member States who do not agree to maintain the current reciprocal arrangements with the UK.
- 2.10 Commission Implementing Decisions 2011/890/EU and 2013/329/EU are being revoked because UK authorities and bodies will no longer be members of these EU networks when the UK is no longer a Member State.

What will it now do?

- 2.11 In a no deal scenario, the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments) (EU Exit) Regulations 2019 will remedy deficiencies in domestic legislation implementing the Directive in England and Wales, which arise from the UK's withdrawal from the EU. The instrument will retire current cross-border healthcare rights under domestic legislation, while at the same time, so far as possible acting unilaterally, protecting patients in a transitional position and enabling transitional continuation (up to 31 December 2020) of cross-border healthcare arrangements with those countries with whom we have established continued reciprocity.
- 2.12 These regulations thus enable England and Wales to continue facilitating people resident in England and Wales to access cross-border healthcare in "listed" countries. The Secretary of State will maintain a list of countries that reach agreement with the UK to continue cross-border healthcare arrangements. However, the regulations extinguish access to healthcare in countries where there is no reciprocity, as maintaining effective access to cross-border healthcare abroad requires basic reciprocity.

- 2.13 This instrument also seeks to protect, so far as possible, key groups of patients in a transitional situation on exit day, irrespective of any reciprocity in place. This covers for example those individuals who obtained authorisation for planned treatment before exit day, but have not yet obtained the treatment and those who accessed healthcare abroad prior to exit day, but have not yet completed the treatment or sought reimbursement. This time-limited measure aims to prevent, so far as is possible without reciprocity, a sudden loss of overseas healthcare rights for residents in England and Wales.
- 2.14 Lastly, the instrument makes miscellaneous amendments to fix deficiencies in retained EU law relating to healthcare arising from EU Exit, such as revoking European Commission Implementing Decisions relating to European Health Networks and omitting references in domestic legislation to EU concepts that will no longer be appropriate.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 The Minister of State for Health considers it appropriate for this instrument to be subject to the affirmative procedure.
- 3.2 The instrument contains provisions which anticipate prospective changes to be made by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, as well as the Social Security Coordination (Reciprocal Healthcare) (Amendment) (EU Exit) Regulations 2019 which are laid in draft alongside this instrument. Footnotes in the instrument indicate where this is the case. Both instruments will be made at the same time to come into force on exit day.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

- 3.3 The territorial application of this instrument varies between provisions.
- 3.4 The territorial application of Parts 2, 3 and 6 of this instrument is the same as the territorial application of each enactment being amended. The territorial application of Part 4 is all of the UK. The territorial application of Part 5 is England and Wales only but the application of the Schedules is the same as the territorial application of each enactment being modified.

4. Extent and Territorial Application

- 4.1 The territorial extent and application of Parts 2, 3 and 6 of this instrument is the same as the territorial extent and application of each enactment being amended.
- 4.2 The territorial extent and application of Part 4 of this instrument is all of the UK.
- 4.3 The territorial extent and application of Part 5 is England and Wales only but the extent and application of the Schedules is the same as the territorial extent and application of each enactment being modified.

5. European Convention on Human Rights

- 5.1 The Minister of State for Health has made the following statement regarding Human Rights:

“In my view the provisions of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019 are compatible with the Convention rights.”

6. Legislative Context

- 6.1 The National Health Service (Cross-Border Healthcare) Regulations 2013 were made under section 2(2) of the European Communities Act 1972 to implement the main elements of the Directive in England and Wales.
- 6.2 The European Communities Act 1972 will be repealed by the EU (Withdrawal) Act 2018 but section 2 of the European Union (Withdrawal) Act 2018 provides for EU-derived domestic legislation to be saved so that it continues to have effect in UK domestic law after exit day. The National Health Service (Cross-Border Healthcare) Regulations 2013 and the amendments they made to other legislation, including the NHS Act 2006 and the NHS (Wales) Act 2006, will therefore be preserved but will require amendment in order to function effectively after exit day.
- 6.3 This instrument also revokes two Commission implementing decisions adopted by the European Commission in relation to the Directive. Those decisions will by virtue of section 3 of the European Union (Withdrawal) Act 2018 form part of UK domestic law after exit day.
- 6.4 Section 8 of the European Union (Withdrawal) Act 2018 provides a power to prevent, remedy or mitigate deficiencies in the EU law retained under that Act that arise from the UK’s withdrawal from the EU. This statutory instrument is being made under section 8 to address deficiencies in retained EU law relating to cross-border healthcare. The amendments made by this instrument will ensure that legislation relating to cross-border healthcare will continue to function effectively in the event that the UK leaves the EU without a deal in place.
- 6.5 A separate instrument, The Health Services (Cross Border Healthcare) (EU Exit) (Amendment) Regulations Northern Ireland 2019, is being laid under section 8 of the European (Withdrawal) Act 2018 to address deficiencies in the retained EU law that will apply to Northern Ireland.
- 6.6 The Healthcare (International Arrangements) Bill, currently before Parliament, will provide the necessary powers to implement any future longer-term reciprocal healthcare arrangements with the EU, individual Member States or countries outside the EU.

7. Policy background

What is being done and why?

- 7.1 In a no deal scenario, intervention is required to create a suitable legislative framework for the Cross-Border Healthcare Directive after we leave the EU. When the UK leaves the EU, the EU (Withdrawal) Act 2018 will automatically retain the legislation implementing the Directive, which would be incoherent as the UK would no longer be a Member State and it would be unclear if patients still had rights to UK funded healthcare in the EU. The lack of a clear legal framework would create legal and operational uncertainty, as well as legal risk in relation to the rights that exist and the processes for implementing them.

- 7.2 Cross-border healthcare arrangements will fail to operate effectively without reciprocity from EEA member states regarding equal treatment and reciprocal healthcare arrangements. If cross-border healthcare arrangements remain in place without agreement to continue the current reciprocal healthcare arrangements (under the Social Security Coordination (Reciprocal Healthcare) (Amendment etc) (EU Exit) Regulations 2019 being brought forward alongside this instrument), there is a risk that the NHS in each of the four nations could become responsible for unilaterally funding overseas treatment that was previously covered by the reciprocal social security arrangements and thus reimbursed state-to-state by DHSC. For example, in the absence of broader EU reciprocal healthcare arrangements, people could choose to use ‘Directive rights’ to claim reimbursement for treatments that were formerly provided under the EHIC scheme and reimbursed state-to-state. Further, without agreement to continue treating citizens equally (with respect to healthcare charging), the cost of treatments for UK patients in the EEA could rise, increasing costs to both the UK and to individuals.
- 7.3 As set out in paragraphs 2.11 to 2.13, this instrument will retire the current cross-border healthcare arrangements giving effect to the Directive in domestic legislation, but at the same time make important savings provisions to protect those in a transitional position on exit day and enable transitional continuation (up to 31 December 2020) of cross-border healthcare arrangements with those countries with whom we have established basic reciprocity.
- 7.4 These regulations thus enable residents in England and Wales to continue accessing cross-border healthcare with “listed” countries. We envisage listing countries that reach agreement with the UK to continue current reciprocal healthcare and cross-border healthcare arrangements for a time-limited period until 31 December 2020. The saving would not apply to countries where there is no reciprocity.
- 7.5 This instrument also seeks to protect so far as possible key groups in a transitional situation on exit day, irrespective of any reciprocity in place. This group covers people who have applied for or obtained authorisation for planned treatment before exit day, though not yet obtained the treatment and those people who accessed healthcare abroad prior to exit day. This time-limited measure is aimed at preventing, so far as possible without reciprocity, the sudden loss of overseas healthcare rights for our residents in England and Wales on exit day.
- 7.6 Cross-border healthcare arrangements are devolved. This instrument addresses the deficiencies that arise in the legislation that implemented the directive in England and Wales. Welsh consent has therefore been sought for this instrument. Consent has also been sought from Northern Ireland and Scotland in respect of the miscellaneous amendments made by this instrument that extend beyond England and Wales, in so far as they consider those amendments to fall within devolved competence.
- 7.7 This instrument is intended to support other preparations the UK Government is making with regard to reciprocal healthcare arrangements.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

- 8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In accordance with the requirements of that Act the

Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

- 9.1 This Statutory Instrument does not involve consolidation and there are no plans to consolidate the relevant legislation at this time.

10. Consultation outcome

- 10.1 Reciprocal healthcare arrangements are popular and enjoy broad support from the general public. The Department of Health and Social Care has not undertaken a consultation on the instrument but has engaged with relevant stakeholders on its approach to the future of EU reciprocal and cross-border healthcare arrangements.

11. Guidance

- 11.1 No further guidance is published alongside this Instrument.
- 11.2 Specific guidance for UK nationals in the EU and EU Citizens in the UK on how to access healthcare is available on www.gov.uk and www.nhs.uk. Further, this Instrument provides for National Contact Points to have functions relating to the provision of information to patients about matters such as treatment providers and patients' rights.

12. Impact

- 12.1 There is no, or no significant, impact on business, charities or voluntary bodies. This Statutory Instrument provides a mechanism for the continuation of cross-border healthcare arrangements with EEA States.
- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

13. Regulating small business

- 13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

- 14.1 As this instrument is made under the EU (Withdrawal Act) 2018, no review clause is required.

15. Contact

- 15.1 Sophie Eltringham at the Department of Health and Social Care. Telephone: 020 7972 4018 or email: Sophie.eltringham@dhsc.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Mayerling O'Regan, Deputy Director for EU and International Health, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Stephen Hammond, Minister of State for Health at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriateness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.

Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the ‘good reasons’ for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister’s opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument’s effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority’s response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) Act 2018

1. Appropriateness statement

- 1.1 The Minister of State for Health, Stephen Hammond, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019 do no more than is appropriate”.

- 1.2 This is the case because they correct deficiencies in retained EU law and, in a no deal scenario, intervention is required to create a suitable legislative framework for cross-border healthcare arrangements to continue after we leave the EU. It will do no more than is appropriate to ensure that the Government can take the necessary steps to continue current EU healthcare coordination arrangements on an interim basis, where there is continued reciprocity, and to cease these arrangements where there is not.

2. Good reasons

- 2.1 The Minister of State for Health, Stephen Hammond, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action”.

- 2.2 These are, as explained in section 2 of the Explanatory Memorandum, when the UK leaves the EU on the ‘exit day’, the EU (Withdrawal) Act 2018 will automatically retain the domestic implementing legislation in UK law if no further secondary legislation is made. In the event of no deal, if we do not legislate further, the regulations would in practice be unworkable without reciprocity and cooperation from EEA Member States.

- 2.3 Without agreement to continue reciprocal healthcare arrangements (provided for by the Social Security Coordination (Reciprocal Healthcare) (Amendment etc) (EU Exit) Regulations 2019), there is a risk that the NHS in each of the four nations could become responsible for unilaterally funding overseas treatment under the Directive route that was previously reimbursed state-to-state by DHSC (e.g. if people choose to use cross-border healthcare arrangements to claim reimbursement for treatments that were formerly provided under the EHIC scheme and reimbursed state-to-state).

3. Equalities

- 3.1 The Minister of State for Health, Stephen Hammond, has made the following statement(s):

“The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.”

3.2 The Minister of State for Health, Stephen Hammond, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In relation to the draft instrument, I, Stephen Hammond, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010.”

3.3 An Equalities analysis has been conducted for this piece of secondary legislation.

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.

5. Legislative sub-delegation

5.1 The Minister of State for Health has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view it is appropriate to create a relevant sub-delegated power in the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019”.

5.2 This instrument makes provision for the Secretary of State to publish and maintain a list specifying the Member States with which the UK has reciprocal arrangements. This list mechanism is appropriate because it can be updated quickly in response to the conclusion of negotiations with Member States to continue cross-border healthcare arrangements with them. The list will be published and accessible to the public so that it is clear which countries continue to operate these cross-border healthcare arrangements with the UK and can provide individuals with certainty about the continuation of those arrangements as soon as negotiations are concluded. Including the list in legislation would delay the UK’s ability to give effect to agreements seeking to maintain the current healthcare arrangements and would require multiple amending instruments as negotiations with different Member States are concluded in advance of exit day.