

Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No.

**EXITING THE EUROPEAN UNION
HEALTH SERVICES
NATIONAL HEALTH SERVICE,
ENGLAND AND WALES
NATIONAL HEALTH SERVICE, SCOTLAND
HEALTH AND PERSONAL SOCIAL
SERVICES, NORTHERN IRELAND
SOCIAL SECURITY
HUMAN TISSUE, ENGLAND AND WALES
HUMAN TISSUE, NORTHERN IRELAND**

The Reciprocal and Cross-Border Healthcare
(Amendment etc.) (EU Exit) Regulations 2020

Made - - - - *****

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018⁽¹⁾, and sections 2(1) and (2)(f) and (h) and 7(2) and (3) of the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019⁽²⁾.

In accordance with paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

(1) 2018 c. 16. Paragraph 21 was amended by paragraphs 38 and 53 of Schedule 5 to the European Union (Withdrawal Agreement) Act 2020 (c. 1).
(2) 2019 c. 14.

In accordance with section 5 of the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019, the Secretary of State has consulted the Scottish Ministers, the Welsh Ministers and the Department of Health in Northern Ireland before making these Regulations.

PART 1

Preliminary

Citation and commencement

1. These Regulations may be cited as the Reciprocal and Cross-Border Healthcare (Amendment etc.) (EU Exit) Regulations 2020 and come into force immediately before IP completion day.

PART 2

Amendment of Reciprocal Healthcare Regulations

Amendment of the Social Security Coordination (Reciprocal Healthcare) (Amendment etc.) (EU Exit) Regulations 2019

2. The Social Security Coordination (Reciprocal Healthcare) (Amendment etc.) (EU Exit) Regulations 2019⁽³⁾ are amended as follows.

Substitution of regulation 6

3. For regulation 6 substitute—

“The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006

6. In the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006⁽⁴⁾, in Schedule 2 (receipt of transplantable material), in paragraph 10, in the text following “case) that—”—

(a) for sub-paragraph (a) (including the “or” at the end) substitute—

“(a) the treatment of the recipient was provided under a listed healthcare arrangement as defined in regulation 1(3) of the Healthcare (European Economic Area and Switzerland Arrangements) (EU Exit) Regulations 2019⁽⁵⁾, or”;

(b) omit sub-paragraph (b).”.

Substitution of regulation 8

4. For regulation 8 substitute—

⁽³⁾ [S.I. 2019/776](#).

⁽⁴⁾ [S.I. 2006/1260](#); relevant amendments were made by [S.I. 2011/1043](#) and [2012/1809](#).

⁽⁵⁾ [S.I. 2019/1293](#).

“The National Health Service (General Medical Services Contracts) Regulations 2015

8. In regulation 74F (information relating to overseas visitors) of the National Health Service (General Medical Services Contracts) Regulations 2015⁽⁶⁾—

- (a) for paragraph (1)(b) (but not the words following that paragraph) substitute—
 - “(b) where applicable in the case of a patient, record the fact that the patient is the holder of a document—
 - (i) which is—
 - (aa) a European Health Insurance Card;
 - (bb) an S1 Healthcare Certificate; or
 - (cc) a document which, for the purposes of a listed healthcare arrangement as defined in regulation 1(3) of the Healthcare (European Economic Area and Switzerland Arrangements) (EU Exit) Regulations 2019, is treated as equivalent to a document referred to in sub-paragraph (aa) (“EHIC equivalent document”) or (bb) (“S1 equivalent document”); and
 - (ii) which has not been issued to or in respect of the patient by the United Kingdom,”;
- (b) in paragraph (2)(a)—
 - (i) after “European Health Insurance Card” insert “or EHIC equivalent document”;
 - (ii) after “that card” insert “or document”;
- (c) in paragraph (4)—
 - (i) after “S1 Healthcare Certificate” insert “or S1 equivalent document”;
 - (ii) after the remaining references to “certificate” (in both places), insert “or document”.”.

Substitution of regulation 9

5. For regulation 9 substitute—

“The National Health Service (Personal Medical Services Agreements) Regulations 2015

9. In regulation 67F (information relating to overseas visitors) of the National Health Service (Personal Medical Services Agreements) Regulations 2015⁽⁷⁾—

- (a) for paragraph (1)(b) (but not the words following that paragraph) substitute—
 - “(b) where applicable in the case of a patient, record the fact that the patient is the holder of a document—
 - (i) which is—
 - (aa) a European Health Insurance Card;
 - (bb) an S1 Healthcare Certificate; or

⁽⁶⁾ S.I. 2015/1862; relevant amendments were made by S.I. 2017/908 and 2020/226.

⁽⁷⁾ S.I. 2015/1879; relevant amendments were made by S.I. 2017/908 and 2020/226.

- (cc) a document which, for the purposes of a listed healthcare arrangement as defined in regulation 1(3) of the Healthcare (European Economic Area and Switzerland Arrangements) (EU Exit) Regulations 2019, is treated as equivalent to a document referred to in sub-paragraph (aa) (“EHIC equivalent document”) or (bb) (“S1 equivalent document”); and
- (ii) which has not been issued to or in respect of the patient by the United Kingdom,”;
- (b) in paragraph (2)(a)—
 - (i) after “European Health Insurance Card” insert “or EHIC equivalent document”;
 - (ii) after “that card” insert “or document”;
- (c) in paragraph (4)—
 - (i) after “S1 Healthcare Certificate” insert “or S1 equivalent document”;
 - (ii) after the remaining references to “certificate” (in both places), insert “or document”.”.

Revocation of regulation 17 and Schedule 5

- 6. Omit regulation 17 and Schedule 5 (savings and transitional provision).

PART 3

Amendment of Cross-Border Healthcare Regulations

Amendment of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc.) (EU Exit) Regulations 2019

- 7. The National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc.) (EU Exit) Regulations 2019⁽⁸⁾ are amended as follows.

Substitution of regulation 9

- 8. For regulation 9 substitute—

“The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004

9.—(1) The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004⁽⁹⁾ are amended as follows.

(2) In Schedule 2 (drugs, medicines and other substances that may be ordered only in certain circumstances), in the entry in column 2 of the table that corresponds to the entry in column 1 relating to drugs for the treatment of erectile dysfunction—

- (a) for sub-paragraph (b) (including the “or” at the end) substitute—
 - “(b) a man who is a national of an EEA State who—

⁽⁸⁾ S.I. 2019/777.

⁽⁹⁾ S.I. 2004/629; relevant amendments were made by S.I. 2011/1043, 2013/2194 and 2014/1625.

- (i) immediately before IP completion day was entitled to treatment by virtue of Article 7(2) of Council Regulation 1612/68 as extended by the EEA Agreement or was entitled to treatment by virtue of any other enforceable EU right;
 - (ii) has erectile dysfunction and was on 14th September 1998 receiving a course of treatment under a national health insurance system of an EEA State for that condition with any of the drugs listed in sub-paragraph (a); and
 - (iii) immediately before IP completion day was receiving a course of treatment as part of the health service for the condition mentioned in paragraph (ii) of this sub-paragraph with any of the drugs listed in sub-paragraph (a); or”;
- (b) for sub-paragraph (c) (including the “or” at the end) substitute—
- “(c) a man who is not a national of an EEA State but who is the member of the family of such a national and who—
- (i) immediately before IP completion day had an enforceable EU right to be treated no less favourably than the national in the provision of medical treatment;
 - (ii) has erectile dysfunction and was on 14th September 1998 receiving a course of treatment for that condition with any of the drugs listed in sub-paragraph (a); and
 - (iii) immediately before IP completion day was receiving a course of treatment as part of the health service for the condition mentioned in paragraph (ii) of this sub-paragraph with any of the drugs listed in sub-paragraph (a); or”.”.

Revocation of regulation 10

9. Omit regulation 10 (amendment of the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004).

Amendment of regulation 15

10. In regulation 15 (cross-border cases arising before exit day), for the words “exit day” wherever they occur (including the heading) substitute “IP completion day”.

Revocation of regulations 16 and 17 and Schedules 2 and 3

11. Omit regulations 16 (cases arising during cross-border arrangements) and 17 (savings provision for cases arising during cross-border arrangements) and Schedules 2 (modifications in relation to regulation 16) and 3 (modifications in relation to regulation 17).

Amendment of Schedule 1

12. In Schedule 1 (cross-border cases – modifications in relation to regulation 15)—

(a) for the words “exit day” wherever they occur (including the heading) substitute “IP completion day”;

(b) after paragraph 1(b) insert—

“(ba) in section 6A(6), after the second reference to “apply” there were inserted “by virtue of Title III of Part 2 of the withdrawal

agreement (co-ordination of social security systems), Title III of Part 2 of the EEA EFTA separation agreement or social security co-ordination provisions of the Swiss citizens' rights agreement (co-ordination of social security systems)";

(bb) after section 6A(11), there were inserted—

“(12) In subsection (6), expressions which are defined in the European Union (Withdrawal Agreement) Act 2020 have the same meaning as they have in that Act.”;

(bc) in section 6BA(9), after “applies” there were inserted “by virtue of Title III of Part 2 of the withdrawal agreement (co-ordination of social security systems), Title III of Part 2 of the EEA EFTA separation agreement or social security co-ordination provisions of the Swiss citizens' rights agreement (co-ordination of social security systems)”;

(bd) after section 6BA(15), there were inserted—

“(16) In subsection (9), expressions which are defined in the European Union (Withdrawal Agreement) Act 2020 have the same meaning as they have in that Act.”;”;

(c) omit paragraph 1(e);

(d) after paragraph 2(b) insert—

“(ba) in section 6A(6), after the second reference to “apply” there were inserted “by virtue of Title III of Part 2 of the withdrawal agreement (co-ordination of social security systems), Title III of Part 2 of the EEA EFTA separation agreement or social security co-ordination provisions of the Swiss citizens' rights agreement (co-ordination of social security systems)”;

(bb) after section 6A(11), there were inserted—

“(12) In subsection (6), expressions which are defined in the European Union (Withdrawal Agreement) Act 2020 have the same meaning as they have in that Act.”;

(bc) in section 6BA(9), after “applies” there were inserted “by virtue of Title III of Part 2 of the withdrawal agreement (co-ordination of social security systems), Title III of Part 2 of the EEA EFTA separation agreement or social security co-ordination provisions of the Swiss citizens' rights agreement (co-ordination of social security systems)”;

(bd) after section 6BA(15), there were inserted—

“(16) In subsection (9), expressions which are defined in the European Union (Withdrawal Agreement) Act 2020 have the same meaning as they have in that Act.”;”;

(e) omit paragraph 2(c);

(f) after paragraph 5(j) insert—

“(ja) in regulation 13(2) (NHS charges), in paragraph (a) of the definition of “cross-border healthcare service”, after “visiting patient”, there were inserted “which insofar as it was provided before IP completion day was provided”;;”;

(g) for paragraph 5(l)(iv) substitute—

- “(iv) in paragraph (3)(b), for “it is not provided” there were substituted “insofar as the service was provided before IP completion day it was not provided”;
- (h) omit paragraph 5(1)(v);
- (i) for paragraph 5(m) substitute—
 - “(m) regulation 16 (review) were omitted;”;
- (j) for paragraph 6 substitute—

“Modifications to the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013

- 6. The NHS Functions Regulations are to be read as if—
 - (a) regulation 2(1)(a) (interpretation) were omitted;
 - (c) in regulation 3 (exercise of functions)—
 - (i) in paragraph (a), for references to “another EEA state” (in both places) there were substituted “an EEA state”;
 - (ii) paragraph (b) were omitted;
 - (c) in regulation 4 (procedure for applications)—
 - (i) after paragraph (1)(a) there were inserted “and”;
 - (ii) paragraph (1)(c) and the “and” before it were omitted;
 - (iii) in paragraph (3)(a), the words “or pursuant to Article 20 or Article 27(3)” were omitted;
 - (d) in regulation 6(2) (form and content of determination)—
 - (i) after sub-paragraph (a) there were inserted “or”;
 - (ii) sub-paragraph (c) and the “or” before it were omitted.”.

PART 4

Amendment of Northern Ireland Cross-Border Healthcare Regulations

Amendment of the Health Services (Cross-Border Healthcare and Miscellaneous Amendments) (Northern Ireland) (EU Exit) Regulations 2019

13. The Health Services (Cross-Border Healthcare and Miscellaneous Amendments) (Northern Ireland) (EU Exit) Regulations 2019(10) are amended as follows.

Amendment of regulations 11, 12 and 16

14. In regulations 11 (saving of Article 14B of the Order of 1972 for pre-exit day cases), 12 (saving of Articles 14D and 14E of the Order of 1972 for pre-exit day cases) and 16 (saving of the 2013 Regulations for pre-exit day cases), for the words “exit day” wherever they occur (including the heading) substitute “IP completion day”.

Amendment of Schedule 1

15. In Schedule 1 (modifications to the 2013 Regulations for pre-exit day cases)—

- (a) for the words “exit day” wherever they occur (including the heading) substitute “IP completion day”;
- (b) omit paragraph 1(e).

Revocation of regulations 13 to 15, 17 and 18 and Schedule 2

16. Omit regulations 13 (further saving of Articles 14D and 14E of the Order of 1972: cross-border arrangements) to 15 (the Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004), 17 (further saving of the 2013 Regulations: cross-border arrangements) and 18 (Provision of Health Services to Persons Not Ordinarily Resident Regulations (Northern Ireland) 2015) and Schedule 2 (modifications to the 2013 Regulations for cross-border arrangements).

Substitution of regulation 19

17. For regulation 19 substitute—

“The Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (Northern Ireland) 2004

19.—(1) The Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (Northern Ireland) 2004~~(11)~~ are amended as follows.

(2) In Schedule 2 (drugs, medicines and other substances that may be ordered only in certain circumstances), in the entry in column 2 of the table relating to patients with erectile dysfunction—

(a) for sub-paragraph (b) (including the “or” at the end) substitute—

“(b) a man who is a national of an EEA State who—

- (i) immediately before IP completion day was entitled to treatment by virtue of Article 7(2) of Council Regulation 1612/68 as extended by the EEA Agreement or was entitled to treatment by virtue of any other enforceable EU right;
- (ii) has erectile dysfunction and was on 14th September 1998 receiving a course of treatment under a national health insurance system of an EEA State for that condition with any of the drugs listed in sub-paragraph (a); and
- (iii) immediately before IP completion day was receiving a course of treatment for the condition mentioned in paragraph (ii) of this sub-paragraph with any of the drugs listed in sub-paragraph (a); or”;

(b) for sub-paragraph (c) (including the “or” at the end) substitute—

“(c) a man who is not a national of an EEA State but who is the member of the family of such a national and who—

- (i) immediately before IP completion day had an enforceable EU right to be treated no less favourably than the national in the provision of medical treatment;
- (ii) has erectile dysfunction and was on 14th September 1998 receiving a course of treatment for that condition with any of the drugs listed in sub-paragraph (a); and

(11) S.R. 2004 No. 142; relevant amendments were made by S.R. 2011 No. 327 and 2014 No. 215.

- (iii) immediately before IP completion day was receiving a course of treatment for the condition mentioned in paragraph (ii) of this sub-paragraph with any of the drugs listed in sub-paragraph (a); or”.”.

PART 5

Consequential amendment

Amendment of the Healthcare (European Economic Area and Switzerland Arrangements) (EU Exit) Regulations 2019

18. In the Healthcare (European Economic Area and Switzerland Arrangements) (EU Exit) Regulations 2019(12), omit regulation 3 (functions relating to transitional reciprocal arrangements).

Date

Name
Minister of State
Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union including deficiencies arising from the end of the implementation period and other effects of the withdrawal agreement.

These Regulations are also made in exercise of the powers in the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 (c. 14).

Part 2 amends the Social Security Coordination (Reciprocal Healthcare) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/776) to reflect certain healthcare entitlements in the withdrawal agreement, the EEA EFTA separation agreement and the Swiss citizens' rights agreement. Regulation 6 omits provisions which would continue on a transitional basis, until 31st December 2020, EU-derived healthcare legislation, namely Regulation (EC) No 883/2004, Regulation (EC) No 987/2009, Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 (as extended by Regulation (EC) No 859/2003).

Part 3 amends the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc.) (EU Exit) Regulations 2019 (S.I. 2019/777). It substitutes references to exit day with references to IP completion day (which is 11 pm on 31st December 2020). Regulation 11 omits provisions which would continue on a transitional basis, until 31st December 2020, legislation relating to cross-border healthcare in England.

Part 4 amends the Health Services (Cross-Border Healthcare and Miscellaneous Amendments) (Northern Ireland) (EU Exit) Regulations 2019 (S.I. 2019/784). It substitutes references to exit day with references to IP completion day, and regulation 16 omits provisions which would continue on a transitional basis, until 31st December 2020, legislation relating to cross-border healthcare in Northern Ireland.

Part 5 makes a miscellaneous consequential amendment.

An impact assessment has not been produced in relation to this instrument. An explanatory memorandum has been published alongside this instrument at www.legislation.gov.uk.