

*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.*

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## DRAFT STATUTORY INSTRUMENTS

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**2019 No. 0000**

# **EXITING THE EUROPEAN UNION, NORTHERN IRELAND HEALTH AND PERSONAL SOCIAL SERVICES**

**The Health Services (Cross-Border Health  
Care and Miscellaneous Amendments)  
(Northern Ireland) (EU Exit) Regulations 2019**

*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 of, and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018<sup>(1)</sup>.

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

## **PART 1**

### **Introductory**

#### **Citation, commencement, interpretation and extent**

1.—(1) These Regulations may be cited as the Health Services (Cross-Border Health Care and Miscellaneous Amendments) (Northern Ireland) (EU Exit) Regulations 2019 and come into force on exit day<sup>(2)</sup>.

(2) In these Regulations—

“the Order of 1972” means the Health and Personal Social Services (Northern Ireland) Order 1972<sup>(3)</sup>;

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<sup>(1)</sup> 2018 c. 16

<sup>(2)</sup> “Exit day” is defined in section 20 of the European Union (Withdrawal) Act 2018

<sup>(3)</sup> S.I. 1972/1265 (N.I. 14)

“the 2013 Regulations” means the Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013(4).

(3) These Regulations extend to Northern Ireland only.

## PART 2

### Cross-border health care

#### CHAPTER 1

##### Amendment of primary legislation

#### **The Health and Personal Social Services (Northern Ireland) Order 1972**

2.—(1) The Order of 1972 is amended as follows.

(2) In Article 2(2) (interpretation) omit the definitions of “EEA agreement”, “EEA state” and “Regulation (EC) No. 883/2004”(5).

(3) Omit Articles 14B to 14E (reimbursement of the cost of health care services secured in another EEA state)(6).

(4) In Article 45 (travelling expenses of patients, etc.)(7) omit paragraph (1)(a)(ii) and (iii).

#### CHAPTER 2

##### Amendment of secondary legislation

#### **Health and Personal Social Services General Dental Services Regulations (Northern Ireland) 1993**

3.—(1) The Health and Personal Social Services General Dental Services Regulations (Northern Ireland) 1993(8) are amended as follows.

(2) In regulation 2 (interpretation) omit the definitions of—

- (a) “the Directive”, and
- (b) “visiting patient”.

(3) In Schedule 2 (terms of service for dentists)—

- (a) in paragraph 3—
  - (i) in sub-paragraph (2)(b)(iv) omit “or”;
  - (ii) omit sub-paragraphs (2)(b)(v) and (3).
- (b) omit paragraph 23A.

#### **Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004**

4.—(1) The Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004(9) are amended as follows.

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(4) S.R. 2013 No. 299 as amended by S.R. 2015 No. 130

(5) The definitions were inserted by S.R. 2012 No. 167

(6) Articles 14B and 14C were inserted by S.R. 2012 No. 167; Articles 14D and 14E were inserted by S.R. 2013 No. 299

(7) Article 45(1)(a) was substituted by S.R. 2012 No. 167 and amended by S.R. 2013 No. 299

(8) S.R. 1993 No. 326 amended by S.R. 2013 No. 300

(9) S.R. 2004 No. 140 as amended by S.R. 2013 No. 301

- (2) In regulation 2 (interpretation) omit the definitions of—
  - (a) “the Directive”, and
  - (b) “visiting patient”.
- (3) In regulation 15 (essential services)—
  - (a) in paragraph (3) for “registered patients, temporary residents and visiting patients”, substitute “registered patients and temporary residents”;
  - (b) in paragraph (5) for “registered patients, temporary residents and visiting patients”, substitute “registered patients and temporary patients”.
- (4) In Schedule 4 (fees and charges), in paragraph 1 omit sub-paragraphs (l) and (m).
- (5) In Schedule 5 (other contractual terms)—
  - (a) in paragraph 3 (attendance outside practice premises), in sub-paragraph (4) omit “or a visiting patient”;
  - (b) omit paragraph 15A (application to the contractor for regulation 15(3) and (5) services);
  - (c) omit paragraph 32A (assignment of a person to a contractor for regulation 15(3) and (5) services);
  - (d) omit paragraph 40(4);
  - (e) omit paragraphs 41(2)(e) and 41(4)(i);
  - (f) in paragraph 78, omit sub-paragraph (2).

#### **The Health Care (Reimbursement of the Cost of EEA Services etc.) Regulations (Northern Ireland) 2012**

5. In the Health Care (Reimbursement of the Cost of EEA Services etc.) Regulations (Northern Ireland) 2012<sup>(10)</sup> omit regulation 4.

#### **The Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013**

6. The 2013 Regulations are revoked.

#### **General Dental Services (Amendment) Regulations (Northern Ireland) 2013**

7. In the General Dental Services (Amendment) Regulations (Northern Ireland) 2013<sup>(11)</sup> omit regulations 2, 3 and 4.

#### **The Health and Personal Social Services (General Medical Services Contracts) (Amendment No. 2) Regulations (Northern Ireland) 2013**

8. In the Health and Personal Social Services (General Medical Services Contracts) (Amendment No. 2) Regulations (Northern Ireland) 2013<sup>(12)</sup> omit regulations 2, 3, 4 and 5(3) to (6).

#### **Provision of Health Services to Persons Not Ordinarily Resident Regulations (Northern Ireland) 2015**

9.—(1) The Provision of Health Services to Persons Not Ordinarily Resident Regulations (Northern Ireland) 2015<sup>(13)</sup> are amended as follows.

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<sup>(10)</sup> S.R. 2012 No. 167

<sup>(11)</sup> S.R. 2013 No. 300

<sup>(12)</sup> S.R. 2013 No. 301

<sup>(13)</sup> S.R. 2015 No. 27

- (2) In regulation 2(1) (interpretation) omit the definitions of—
- (a) “[Directive 2011/24/EU](#)”,
  - (b) “out of hours period”,
  - (c) “out of hours provider”,
  - (d) “out of hours services”, and
  - (e) “visiting patient”.
- (3) Omit regulation 25(visiting patients under [Directive 2011/24/EU](#)).

### **The Health Services (Cross-Border Health Care) (Amendment) Regulations (Northern Ireland) 2015**

**10.** The Health Services (Cross-Border Health Care) (Amendment) Regulations (Northern Ireland) 2015(**14**) are revoked.

## **CHAPTER 3**

### **Savings**

#### **Saving of Article 14B of the Order of 1972 for pre-exit day cases**

**11.—**(1) Despite the revocations made by regulations 2, 5, and 6, Article 14B of the Order of 1972 continues to have effect on and after exit day in relation to any qualifying EEA expenditure which was incurred on or after 10 May 2012 and before 27 December 2013 and was not reimbursed under that Article before exit day.

(2) In Article 14B as saved by this regulation, paragraph (5) is to be read as if for the words “circumstances where Article 20 or 27(3) of Regulation ([EC](#)) No. 883/2004 applies” there were substituted “circumstances where, immediately before exit day, Article 20 or 27(3) of Regulation ([EC](#)) No. 883/2004 would have applied”.

(3) The definition of “Regulation ([EC](#)) No. 883/2004” in Article 2(2) of the Order of 1972 continues to have effect for the purposes of Article 14B as saved by this regulation, but as if in that definition there were inserted at the end “as that Regulation had effect immediately before exit day”.

(4) In Article 14B as saved by this regulation “EEA state” has the meaning given by Schedule 1 to the Interpretation Act 1978(**15**).

(5) In this regulation “qualifying EEA expenditure” has the same meaning as in Article 14B of the Order of 1972 as that Article had effect immediately before exit day.

#### **Saving of Articles 14D and 14E of the Order of 1972 for pre-exit day cases**

**12.—**(1) This regulation applies despite the revocations made by regulations 2, 5, and 6.

(2) Article 14D of the Order of 1972 continues to have effect on and after exit day in relation to qualifying EEA expenditure which—

- (a) was incurred (and not reimbursed under that Article) before exit day,
- (b) was incurred on or after exit day on the provision of a service which was provided, or began to be provided, before exit day, or
- (c) was incurred on or after exit day on the provision of a service that was authorised under Article 14E of that Order—

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(14) [S.R. 2015 No. 130](#)

(15) [1978 c. 30](#)

- (i) before exit day, or
  - (ii) on or after exit day on an application under Article 14E made before exit day.
- (3) But nothing in this regulation—
  - (a) requires reimbursement of qualifying EEA expenditure incurred on the provision of a service which was provided after the later of—
    - (i) the end of one year beginning immediately after the day on which exit day falls, or
    - (ii) where an authorisation for the provision of the service specified a period within which the service must be provided, the end of the specified period.
- (4) In Article 14D as saved by this regulation, paragraph (9) is to be read as if for the words “circumstances where Article 20 or 27(3) of Regulation (EC) No. 883/2004 applies” there were substituted “circumstances where, immediately before exit day, Article 20 or 27(3) of Regulation (EC) No. 883/2004 would have applied”.
- (5) Article 14E of the Order of 1972 continues to have effect on and after exit day in relation to an application for authorisation under that Article which was made, but not determined, before exit day.
- (6) The following definitions continue to have effect for the purposes of Articles 14D and 14E of the Order of 1972 as saved by this regulation—
  - (a) the definitions in Article 14B of that Order which are applied by Article 14D(15) as saved by this regulation, and
  - (b) the definitions in Article 2(2) of the Order of 1972 of “Regulation (EC) No. 883/2004”, but as if there were inserted at the end of that definition “as that Regulation had effect immediately before exit day”.
- (7) Any reference to an EEA state other than the United Kingdom—
  - (a) in Article 14D as saved by this regulation , or
  - (b) in a definition applied by Article 14D(15) as so saved,is to be read in relation to times after exit day as a reference to an EEA state.
- (8) In that Article and in any such definition, “EEA state” has the meaning given by Schedule 1 to the Interpretation Act 1978.
- (9) In this regulation “qualifying EEA expenditure”, and “service” have the same meaning as in Article 14D of the Order of 1972 as that Article had effect immediately before exit day (except that, for the purposes of this paragraph, references in that Article or in any definition applied by paragraph (15) of that Article to an EEA state other than the United Kingdom are to be read, in relation to times after exit day, as references to an EEA state).

#### **Further saving of Articles 14D and 14E of the Order of 1972: cross-border arrangements**

- 13.—**(1) This regulation applies despite the revocations made by regulations 2, 5, and 6.
- (2) In relation to relevant qualifying EEA expenditure, Article 14D of the Order of 1972 continues to have effect on and after exit day but as if—
- (a) in the heading, for “another EEA state” there were substituted “an EEA state”,
  - (b) in paragraph (4), for “an EEA state other than the United Kingdom” there were substituted “an EEA state”, and
  - (c) in paragraph (15), for the words from “authorised provider” to the end there were substituted—
    - ““authorised provider” in relation to any service provided in an EEA state means a person who is lawfully providing that service;

“eligible person” means a person who is ordinarily resident in Northern Ireland;

“health care charge” means a charge payable by virtue of this Order or Article 20(1) of the Health Services (Primary Care) (Northern Ireland) Order 1997<sup>(16)</sup>;

“service” includes any goods, including drugs, medicines, and appliances which are used or supplied in connection with the provision of a service, but does not include accommodation other than hospital accommodation.”

(3) In this regulation “relevant qualifying EEA expenditure” means expenditure which—

- (a) does not fall within regulation 12(2), but
- (b) is qualifying EEA expenditure (within the meaning of Article 14D of the Order of 1972 as modified by this regulation) that was incurred on the provision of a qualifying service.

(4) In paragraph (3) “a qualifying service” means a service that—

- (a) was provided, or began to be provided, in an EEA state within a period that was a relevant period in relation to that state, or
- (b) was authorised under Article 14E of that Order—
  - (i) within a period that was a relevant period in relation to the EEA state where the service was provided, or
  - (ii) on an application under Article 14E made within such a period.

(5) But nothing in this regulation requires reimbursement of expenditure incurred on the provision of a service which was provided in an EEA state after the later of—

- (a) the end of one year beginning with the end of the period that is the relevant period in relation to that state, or
- (b) where an authorisation for the provision of the service specified a period within which the service must be provided, the end of the specified period.

(6) Article 14E of the Order of 1972 has effect on and after exit day in relation to an application for authorisation under that Article which is made within a period that is a relevant period in relation to the EEA state where the service in question would be provided.

(7) In this regulation a “relevant period”, in relation to an EEA state, means a period for which, according to the list maintained by the Secretary of State under regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019, cross-border arrangements between the United Kingdom and that EEA state have effect<sup>(17)</sup>.

(8) Arrangements are cross-border arrangements for the purposes of this regulation if they are arrangements between the United Kingdom and an EEA state that—

- (a) concern cross-border healthcare within the meaning of regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019, and
- (b) give rise to an obligation, in relation to reimbursement of expenditure on the provision of the service in question, that would be met if the expenditure were reimbursed under Article 14D of the Order of 1972.

(9) The definition in Article 2(2) of the Order of 1972 of “Regulation (EC) No. 883/2004” continues to have effect for the purposes of Articles 14D and 14E as saved by this regulation, but as if in that definition there were inserted at the end “as continued by regulation 17 of, and Schedule 5 to, the Social Security Coordination (Reciprocal Healthcare) (Amendment etc) (EU Exit) Regulations 2019)”<sup>(18)</sup>.

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<sup>(16)</sup> S.I. 1997/1177 (N.I. 7)

<sup>(17)</sup> xxx

<sup>(18)</sup> xxx

(10) In Articles 14D and 14E as saved by this regulation “EEA state” has the meaning given by Schedule 1 to the Interpretation Act 1978.

(11) In this regulation “service” has the same meaning as in Article 14D(15) of the Order of 1972 as modified by paragraph (2).

### **Health and Personal Social Services General Dental Services Regulations (Northern Ireland) 1993**

**14.**—(1) In any relevant period, Schedule 2 to the Health and Personal Social Services General Dental Services Regulations (Northern Ireland) 1993 has effect—

- (a) as if the revocations made by regulation 3(2)(b) and (3) of these regulations had not been made, and
- (b) as if, in the definition of “visiting patient” in regulation 2 of those Regulations, for the words from “an individual” to the end there were substituted a reference to an individual who is a relevant patient in that period.

(2) In this regulation a “relevant period” means a period for which, according to the list maintained by the Secretary of State under regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019, any cross-border arrangements have effect.

(3) For the purposes of this regulation an individual is a “relevant patient” in any relevant period if the individual is from an EEA state and, according to that list, cross-border arrangements with that EEA state have effect in that period.

(4) In this regulation “cross-border arrangements” means arrangements between the United Kingdom and an EEA state that concern cross-border healthcare within the meaning of regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019.

### **The Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004**

**15.**—(1) In any relevant period, regulation 15 and Schedules 4 and 5 to the Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004 have effect—

- (a) as if the revocations made by regulation 4(2)(b) and (3) to (5) of these regulations had not been made, and
- (b) as if, in paragraph (a) of the definition of “visiting patient” in regulation 2 of those regulations, for the words from “an individual” to “the Directive” there were substituted a reference to an individual who is a relevant patient in that period.

(2) Paragraphs (2) to (4) of regulation 14 apply for the purposes of this regulation as they apply for the purposes of that regulation.

### **Saving of the 2013 Regulations for pre-exit day cases**

**16.**—(1) In relation to a case where paragraph (2) or (3) applies, the 2013 Regulations continue to have effect on and after exit day in so far as they relate to the National Contact Point and visiting patients as if the revocations made by regulations 6 and 10 of these Regulations had not been made, but with the modifications set out in Schedule 1.

(2) This paragraph applies where—

- (a) a service within Article 14B(3) or Article 14D(4) of the Order of 1972 was provided or began to be provided, or was authorised to be provided, before exit day, or

(b) an application for authorisation under Article 14E of that Order was made before exit day.

(3) This paragraph applies where a cross-border healthcare service was provided or began to be provided to a visiting patient before exit day in the circumstances referred to in Regulation 11 (health care charges) or regulation 12 (exemption from health care charges for certain persons who reside in another member State) of the 2013 Regulations.

(4) But nothing in this regulation imposes an obligation in relation to a charge to a visiting patient for a service which was provided after the end of one year beginning immediately after the day on which exit day falls.

(5) In this regulation “charge”, “cross-border healthcare service” and “visiting patient” have the same meaning as they had in the 2013 Regulations immediately before exit day.

#### **Further saving of the 2013 Regulations: cross-border arrangements**

**17.—**(1) In relation to a relevant period, the 2013 Regulations continue to have effect in so far as they relate to the National Contact Point and visiting patients as if the revocations made by regulations 6 and 10 of these Regulations had not been made but with the modifications set out in Schedule 2.

(2) In this regulation “relevant period” has the same meaning as in regulation 14(2).

#### **Provision of Health Services to Persons Not Ordinarily Resident Regulations (Northern Ireland) 2015**

**18.—**(1) In any relevant period, regulation 25 of the Provision of Health Services to Persons Not Ordinarily Resident Regulations (Northern Ireland) 2015 has effect—

(a) as if the revocations made by regulation 9(2)(b) to (e) and (3) of these regulations had not been made, and

(b) as if—

(i) in the definition of “visiting patient” in regulation 2(1) of those regulations, for the words from “an individual” to the end there were substituted a reference to an individual who is a relevant patient in that period,

(ii) in the heading to regulation 25 of those regulations the words “under [Directive 2011/24/EU](#)” were omitted, and

(iii) in paragraph (1) of that regulation the words “exercising rights under [Directive 2011/24/EU](#)” were omitted.

(2) Paragraphs (2) to (4) of regulation 14 apply for the purposes of this regulation as they apply for the purposes of that regulation.

## **PART 3**

### **Miscellaneous amendments**

#### **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<sup>(19)</sup> are amended as follows.

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(19) [S.R. 2004 No. 142](#) as amended by [S.R. 2014 No. 215](#)



(2) In Schedule 2 (drugs, medicines and other substances that may only be ordered in certain circumstances)—

(a) in the table relating to drugs for the treatment of erectile dysfunction, in column 2 of the table—

(i) in paragraph (b)—

(aa) for “is entitled to treatment” substitute “who immediately before exit day was entitled to treatment”;

(bb) for “enforceable Community right” substitute “enforceable EU right”;

(ii) in paragraph (c), for “who has an enforceable Community right” substitute “who immediately before exit day had an enforceable EU right”.

(b) After the definition of “EEA State” there were inserted—

““enforceable EU right” has the meaning given by section 2(1) of the European Communities Act 1972<sup>(20)</sup> (as that Act had effect immediately before its repeal by section 1 of the European Union (Withdrawal) Act 2018).”.

## PART 4

### Supplementary

#### EU-derived rights

**20.**—(1) EU-derived rights, powers, liabilities, obligations, restrictions, remedies and procedures cease to be recognised and available in domestic law so far as they are inconsistent with, or are otherwise capable of affecting the interpretation, application or operation of, provision made by these regulations.

(2) In this regulation “EU-derived rights, powers, liabilities, obligations, restrictions, remedies and procedures” means any rights, powers, liabilities, obligations, restrictions, remedies and procedures which continue to be recognised and available in domestic law by virtue of section 4 of the European Union (Withdrawal) Act 2018 (including as they are modified by domestic law from time to time).

(3) In this regulation “domestic law” means the law of Northern Ireland.

Signed by the authority of the Secretary of State for Health and Social Care.

Address  
Date

*Name*  
Minister of State,  
Department of Health and Social Care

## SCHEDULE 1

Regulation 16

## Modifications to the 2013 Regulations for pre-exit day cases

1. The modifications of the 2013 Regulations referred to in regulation 16 are that those Regulations are to be read as if—

- (a) in regulation 2 (interpretation)—
  - (i) in the definition of “resident patient”, for “the United Kingdom is” there were substituted “immediately before exit day the United Kingdom was”;
  - (ii) in the definition of “visiting patient”, for “a member State other than the United Kingdom is” there were substituted “immediately before exit day a member State other than the United Kingdom was”;
- (b) in the heading to regulation 5 (national contact point: information about treatment in another member State), for “another member State” there were substituted “a member State”;
- (c) in regulation 5—
  - (i) for references to “other member States” there were substituted “member States”;
  - (ii) for the reference to “another member State” there were substituted “a member State”;
- (d) regulation 5A (National Contact Point: information about prescriptions intended to be used in another member State) were omitted;
- (e) for regulation 6(1) (National Contact Point: cross-border co-operation) there were substituted—
 

“(1) In so far as it considers it appropriate for the purposes of giving effect to regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019, the NCP must co-operate with the national contact points in member States and any other national contact points established in the United Kingdom.”;
- (f) regulation 7 (National Contact Point: duty to consult) were omitted;
- (g) in regulation 12—
  - (i) in paragraph (2) for “P is” there were substituted “immediately before exit day P was”;
  - (ii) in paragraph (2)(a), for “is resident” there were substituted “was resident”;
  - (iii) in paragraph (2)(b), for “is the competent member State” there were substituted “was the competent member State”;
  - (iv) in paragraph (4)(b) at the end there were inserted “as it had effect immediately before exit day”;
- (h) the schedule (elements that must be included in prescriptions intended to be used in another member State) were omitted.

## SCHEDULE 2

Regulation 17

## Modifications to the 2013 Regulations for cross-border arrangements

1. The modifications of the 2013 Regulations referred to in regulation 17 are that those Regulations are to be read as if—

- (a) in regulation 2 (interpretation)—

- (i) after the definition of “the Board” there were inserted—
  - ““cross-border arrangements” has the same meaning as in regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019;”;
- (ii) the definition of “the Directive” were omitted;
- (iii) in the definition of “health care provider” for “member State” there were substituted “relevant member State”;
- (iv) for the definition of “prescription”, there were substituted—
  - ““prescription” means a prescription for a medicinal product issued by a person who is practising in a profession included in the list published under regulation 214(6A)(**21**) of the Human Medicines Regulations(**22**) in a member State that is included in that list in relation to that profession;”
- (v) after the definition of “prescription” there were inserted—
  - ““relevant member State” means a member State which is included in the list maintained under regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019;
  - “relevant period” in relation to an EEA state, means the period during which cross-border arrangements between the United Kingdom and that state have an effect;”;
- (vi) for the definition of “resident patient”, there were substituted—
  - ““resident patient” means an individual to whom the United Kingdom is responsible for granting authorisation for the provision of healthcare in a relevant member State under cross-border arrangements;”;
- (vii) for the definition of “visiting patient”, there were substituted—
  - ““visiting patient” means an individual to whom a relevant member State is responsible for granting authorisation for the provision of healthcare in the United Kingdom under cross-border arrangements;”;
- (b) in regulation 3 (national contact point: designation), for the references to “the Directive” there were substituted “cross-border arrangements”;
- (c) in the heading to regulation 5 (national contact point: information about treatment in another member State), for “another member State” there were substituted “a relevant member State”;
- (d) in regulation 5—
  - (i) for “other member States” there were substituted references to relevant member States”;
  - (ii) for “another member State” there were substituted “a relevant member State”;
- (e) in the heading to regulation 5A (national contact point: information about prescriptions intended to be used in another member State), for “another member State” there were substituted “the United Kingdom”;
- (f) for regulation 5A there were substituted—
  - “**5A.** The NCP must make available to patients information about the elements, specified in the Schedule, to be included in a prescription which is—

(21) Paragraph (6A) is inserted into the Human Medicines Regulations 2012 by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

(22) [S.I. 2012/1916](#)

- (1) issued in a member State included in the list published under regulation 214(6A) of the Human Medicines Regulations 2012, and
- (2) intended to be used in the United Kingdom.”;
- (g) for regulation 6(1) (national contact point: cross-border co-operation) there were substituted—
  - “(1) In so far as it considers it is appropriate for the purposes of giving effect to cross-border arrangements, the NCP must co-operate with the national contact points in relevant member States and any other NCPs established in the United Kingdom.”;
- (h) in regulation 7 (national contact point: duty to consult) for the words from “the Directive” to “in these Regulations,” there were substituted “cross-border arrangements”;
- (i) in regulation 10(1) (information on rights and entitlements) for “mentioned in Article 5(b) of the Directive” there were substituted “under cross-border arrangements”;
- (j) in regulation 11 (health care charges) in paragraph (2), in sub-paragraph (a) of the definition of “cross-border healthcare service”, for “under the Directive” there were substituted “under cross-border arrangements”;
- (k) in the heading to regulation 12 (exemption from healthcare charges for certain persons who reside in another member State), for “another member State” there were substituted “a relevant member State”;
- (l) in regulation 12—
  - (i) in paragraph (2)(a), for “a member State other than the United Kingdom” there were substituted “a relevant member State”;
  - (ii) in paragraph (4)(b) at the end there were inserted “as continued by regulation 17 of, and Schedule 5 to, the Social Security Coordination (Reciprocal Healthcare) (Amendment etc) (EU Exit) Regulations 2019”;
- (m) in the heading to the Schedule (elements that must be included in prescriptions intended to be used in another member State)(23) for the reference to “another member State” there were substituted “the United Kingdom”;
- (n) in the Schedule—
  - (i) in paragraph 4(a), for “Article 1” to the end there were substituted “regulation 8(1) of the Human Medicines Regulations 2012”;
  - (ii) in paragraph 4(b)(i) at the end there were inserted “as modified by Schedule 8B to the Human Medicines Regulations 2012”;
  - (iii) in paragraph 4(e), “as defined in Article 1 of [Directive 2001/83/EC](#)” were omitted.

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(23) the Schedule was inserted by [S.R. 2015 No. 130](#)

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made in exercise of the powers conferred by section 8 of the European Union (Withdrawal) Act 2018 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.

These Regulations amend the Health and Personal Social Services (Northern Ireland) Order 1972, the Health and Personal Social Services General Dental Services Regulations (Northern Ireland) 1993, the Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004, the Health Care (Reimbursement of the Cost of EEA Services etc.) Regulations (Northern Ireland) 2012, the Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013, the General Dental Services (Amendment) Regulations (Northern Ireland) 2013, the Health and Personal Social Services (General Medical Services Contracts) (Amendment No. 2) Regulations (Northern Ireland) 2013, the Provision of Health Services to People Not Ordinarily Resident Regulations (Northern Ireland) 2015, the Health Services (Cross-Border Health Care) (Amendment) Regulations (Northern Ireland) 2015, and the Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc.) Regulations (Northern Ireland) 2004, to amend access to Cross-Border Health Care to visiting patients as a result of the UK's exit/withdrawal from the European Union.

An impact assessment has been prepared for this instrument however it has no impact on businesses, charities or the voluntary sector.