

*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**

**NATIONAL HEALTH SERVICE, ENGLAND AND  
WALES**

**CONSTITUTIONAL LAW**

**DEVOLUTION, WALES**

**LOCAL GOVERNMENT, ENGLAND**

**SOCIAL SECURITY**

**The National Health Service (Cross-Border Healthcare and  
Miscellaneous Amendments etc.) (EU Exit) Regulations 2019**

*Made* - - - -

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*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(a).

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

### Preliminary

#### Citation, commencement, interpretation and extent

1.—(1) These Regulations may be cited as the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc.) (EU Exit) Regulations 2019 and come into force on exit day<sup>(a)</sup>.

(2) In these Regulations—

“the NHS Act 2006” means the National Health Service Act 2006<sup>(b)</sup>;

“the NHS (Wales) Act” means the National Health Service (Wales) Act 2006<sup>(c)</sup>;

“the 2013 Regulations” means the National Health Service (Cross-Border Healthcare) Regulations 2013<sup>(d)</sup>;

“the NHS Functions Regulations” means the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013<sup>(e)</sup>.

(3) An amendment, repeal or revocation made by these Regulations has the same extent and application as the provision being amended, repealed or revoked.

(4) The amendments, repeals and revocations made by Parts 2 and 3 take effect subject to the provisions made by Part 5 of these Regulations.

## PART 2

### Amendments to primary legislation

#### The Health and Social Security Act 1984

2.—(1) The Health and Social Security Act 1984<sup>(f)</sup> is amended as follows.

(2) Omit section 10 (reimbursement of cost of medical and maternity treatment in member States of European Economic Community).

(3) In section 26(4) (extent) omit “section 10”.

#### The National Health Service Act 2006

3. In the NHS Act 2006 omit the following provisions—

(a) section 6A (reimbursement of cost of services provided in another EEA state)<sup>(g)</sup>;

(b) section 6B (prior authorisation for the purposes of section 6A)<sup>(h)</sup>;

(c) section 6BA (reimbursement of cost of services provided in another EEA state where expenditure incurred on or after 25 October 2013)<sup>(i)</sup>;

(d) section 6BB (prior authorisation for the purposes of section 6BA)<sup>(j)</sup>;

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(a) Section 20(1) of the European Union (Withdrawal) Act 2018 defines “exit day”.

(b) 2006 c.41.

(c) 2006 c.42.

(d) S.I. 2013/2269; as amended by S.I. 2015/139 and 238.

(e) S.I. 2013/261; amended by S.I. 2013/2269; there are other amending instruments but none is relevant.

(f) 1984 c.48. Functions under section 10 were, so far as exercisable in relation to Wales, transferred to the National Assembly for Wales by article 2 of, and Schedule 1 to, S.I. 1999/672; those functions are now exercisable by the Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c.32).

(g) Section 6A was inserted by S.I. 2010/915 and amended by paragraph 3 of Schedule 4 to the Health and Social Care Act 2012 (c.7) (“the 2012 Act”) and S.I. 2013/2269.

(h) Section 6B was inserted by S.I. 2010/915 and amended by paragraph 4 of Schedule 4 to the 2012 Act.

(i) Section 6BA was inserted by S.I. 2013/2269.

(j) Section 6BB was inserted by S.I. 2013/2269.

- (e) section 6D (regulations relating to EU obligations)(a);
- (f) section 6E(7)(b) (regulations as to the exercise of functions by the Board or clinical commissioning groups)(b);
- (g) section 183(a)(ii) (payment of travelling expenses)(c);
- (h) the definition of “Regulation (EC) No. 883/2004” in section 275(1) (interpretation)(d) except in so far as it relates to section 183(a)(iii).

#### **The National Health Service (Wales) Act 2006**

- 4.**—(1) The NHS (Wales) Act is amended as follows.
- (2) In section 46 (GMS contracts: prescription of drugs, etc)—
- (a) in subsection (3), for “Community marketing authorization or United Kingdom” substitute “UK”;
  - (b) for subsection (4) substitute—
 

“(4) “UK marketing authorisation” has the meaning given by regulation 8(1) of the Human Medicines Regulations 2012 (S.I. 2012/1916).”.
- (3) Omit the following provisions—
- (a) section 6A (reimbursement of cost of services provided in another EEA state)(e);
  - (b) section 6B (prior authorisation for the purposes of section 6A)(f);
  - (c) section 6BA (reimbursement of cost of services provided in another EEA state where expenditure incurred on or after 25 October 2013)(g);
  - (d) section 6BB (prior authorisation for the purposes of section 6BA)(h);
  - (e) section 131(a)(ii) (payment of travelling expenses)(i);
  - (f) the definition of “Regulation (EC) No. 883/2004” in section 206(1) (interpretation)(j) except in so far as it relates to section 131(a)(iii).

#### **The Health and Social Care Act 2012**

- 5.** In the Health and Social Care Act 2012(k) omit the following provisions—
- (a) section 124(9) (local modifications of prices: agreements);
  - (b) section 125(9) (local modifications of prices: applications).

#### **The Cities and Local Government Devolution Act 2016**

- 6.** In the Cities and Local Government Devolution Act 2016(l) omit section 18(2)(b) (devolving health service functions).

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(a) Section 6D was inserted by section 19 of the 2012 Act.

(b) Section 6E was inserted by section 20 of the 2012 Act.

(c) Section 183(a) was substituted by S.I. 2010/915 and amended by paragraph 98 of Schedule 4 to the 2012 Act and by S.I. 2013/2269.

(d) The definition was inserted by S.I. 2010/915.

(e) Section 6A was inserted by S.I. 2010/915 and amended by S.I. 2013/2269.

(f) Section 6B was inserted by S.I. 2010/915 and amended by S.I. 2013/2269.

(g) Section 6BA was inserted by S.I. 2013/2269.

(h) Section 6BB was inserted by S.I. 2013/2269.

(i) Section 131(a) was substituted by S.I. 2010/915 and amended by S.I. 2013/2269.

(j) The definition was inserted by S.I. 2010/915.

(k) 2012 c.7.

(l) 2016 c.1.

## PART 3

### Amendments to secondary legislation

#### **The Welsh Ambulance Services National Health Service Trust (Establishment) Order 1998**

7. The Welsh Ambulance Services National Health Service Trust (Establishment) Order 1998(a) is amended as follows—

- (a) in article 1(2) (interpretation), omit the definitions of “Directive 2011/24/EU” and “National Contact Point”;
- (b) omit article 3(2)(d) (nature and functions of the trust) but not the “and” after it.

#### **The National Assembly for Wales (Transfer of Functions) Order 1999**

8. In Schedule 1 (enactments conferring functions transferred by article 2) to the National Assembly for Wales (Transfer of Functions) Order 1999(b) omit the entry relating to the Health and Social Security Act 1984.

#### **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(c) are amended as follows.

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

- (a) 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—
  - (i) in paragraph (b), before “by virtue of any other enforceable EU right” insert “who immediately before exit day was entitled to treatment”;
  - (ii) in paragraph (c), for “who has an enforceable EU right” substitute “who immediately before exit day had an enforceable EU right”.

#### **The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004**

10.—(1) The National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004(d) are amended as follows.

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

- (a) 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—
  - (i) in paragraph (b), before “by virtue of any other enforceable EU right” insert “who immediately before exit day was entitled to treatment”;
  - (ii) in paragraph (c), for “who has an enforceable EU right” substitute “who immediately before exit day had an enforceable EU right”.

#### **The National Health Service (Cross-Border Healthcare) Regulations 2013**

11. The 2013 Regulations are revoked.

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(a) S.I. 1998/678; relevant amendments were made by S.I. 2013/2729.

(b) S.I. 1999/672; to which there are amendments not relevant to these Regulations.

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

(d) S.I. 2004/1022 (W.119); relevant amendments were made by S.I. 2011/1043 and 2014/109.

## **The National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013**

**12.**—(1) The NHS Functions Regulations<sup>(a)</sup> are amended as follows.

(2) Omit the following provisions—

- (a) regulation 3(a) (exercise of functions);
- (b) regulation 4(1)(a) and (b) (procedure for applications);
- (c) regulation 6(2)(a) and (b) (form and content of determination);
- (d) regulation 7(3) and (4) (CCGs);
- (e) regulation 8 (applications made before 1st April 2013).

(3) For regulation 4(3)(a) substitute—

“(a) information about the procedures the Board has in place for prior authorisation pursuant to Article 20 or Article 27(3);”

### **PART 4**

#### **Revocation of retained direct EU legislation**

##### **2011/890/EU: Commission Implementing Decision**

**13.** 2011/890/EU: Commission Implementing Decision of 22 December 2011 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth is revoked.

##### **2013/329/EU: Commission Implementing Decision**

**14.** 2013/329/EU: Commission Implementing Decision of 26 June 2013 providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment is revoked.

### **PART 5**

#### **Savings and Transitional Provision**

##### **Cross-border cases arising before exit day**

**15.**—(1) The legislation referred to in Parts 2 and 3, except for regulations 2, 4(2), 8, 9 and 10 is to continue to apply on and after exit day without the amendments, repeals and revocations made by those Parts, and with the modifications made by Schedule 1 in a case where any of paragraphs (2) to (5) apply.

(2) This paragraph applies where a service that satisfied the condition in section 6A(3) or (4) or 6BA(4) or (7) of the NHS Act 2006 or the NHS (Wales) Act was provided, or began to be provided, before exit day.

(3) This paragraph applies where an application for authorisation under section 6B or 6BB of the NHS Act 2006 or the NHS (Wales) Act has been made, but not determined, before exit day.

(4) This paragraph applies where authorisation has been given under section 6B or 6BB of the NHS Act 2006 or the NHS (Wales) Act before exit day.

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(a) S.I. 2013/261; relevant amendments were made by S.I. 2013/2269; there are other amending instruments but none are relevant.

(5) This paragraph applies where a cross-border healthcare service was provided or began to be provided to a visiting patient before exit day.

(6) Nothing in this regulation—

- (a) requires reimbursement in respect of a service which was provided after the later of—
  - (i) the end of the period of one year beginning with the day after the day on which exit day falls, or
  - (ii) in a case where the authorisation for the service authorises the service to be provided within a specified period, the end of the specified period;
- (b) imposes an obligation in relation to a charge to a visiting patient for a service which was provided after the end of the period of one year beginning with the day after the day on which exit day falls.

(7) In this regulation—

“cross-border healthcare service” and “visiting patient” have the same meaning as in the 2013 Regulations;

“service” is to be construed in accordance with section 6A or section 6BA of the NHS Act 2006 or, as the case may be, of the NHS (Wales) Act.

### **Cases arising during cross-border arrangements**

**16.—**(1) The legislation referred to in Parts 2 and 3, except for regulations 2, 4(2), 8, 9 and 10, is to continue to apply on and after exit day without the amendments, repeals and revocations made by those Parts, and with the modifications made by Schedule 2, so far as relating to—

- (a) reimbursement of qualifying EEA expenditure;
- (b) authorisation in relation to the provision of a service in an EEA State;
- (c) the charge to a visiting patient for the provision of a cross-border healthcare service;
- (d) functions relating to National Contact Points.

(2) The legislation applied by paragraph (1) has effect so as to impose an obligation relating to—

- (a) reimbursement of qualifying EEA expenditure,
- (b) authorisation in relation to the provision of a service in an EEA State, or
- (c) the charge to a visiting patient for the provision of a cross-border healthcare service,

only if, and only during the period when, cross-border arrangements have effect between the United Kingdom and the EEA State in question or, in the case of sub-paragraph (c), the member State which is the visiting patient’s member State of affiliation within the meaning of Article 3(c) of the Directive.

(3) For the purposes of this regulation—

- (a) arrangements between the United Kingdom and an EEA State concerning cross-border healthcare are cross-border arrangements if and only if the EEA State is included in the list maintained by the Secretary of State under paragraph (4);
- (b) cross-border arrangements between the United Kingdom and an EEA State are to be treated as beginning and ceasing to have effect at the times specified in the list maintained by the Secretary of State under paragraph (4).

(4) The Secretary of State must maintain a list for the purposes of paragraph (3).

(5) The list must specify in relation to each EEA State listed in it—

- (a) when cross-border arrangements between the EEA State and the United Kingdom are to be treated as beginning to have effect;
- (b) when cross-border arrangements between the EEA State and the United Kingdom are to be treated as ceasing to have effect.

(6) The time specified in the list as the time when cross-border arrangements are to be treated as beginning to have effect may not be before exit day.

(7) The time specified in the list as the time when cross-border arrangements are to be treated as ceasing to have effect may not be after 31 December 2020.

(8) The Secretary of State may remove an EEA State from the list before the time specified in the list as the time when the EEA State's cross-border arrangements are to be treated as beginning to have effect.

(9) The Secretary of State may change a time specified in the list (but not after the time specified).

(10) The Secretary of State must publish the list and keep it up to date.

(11) This regulation is without prejudice to regulation 15.

(12) In this regulation—

“cross-border healthcare service”, “healthcare”, “National Contact Point” and “visiting patient” have the same meaning as in the 2013 Regulations;

“cross-border healthcare”, except in the phrase “cross-border healthcare service”, means—

(a) healthcare provided in an EEA State, payments in respect of which may be made by the government of the United Kingdom; or

(b) healthcare provided in the United Kingdom, payments in respect of which may be made by an EEA State;

“the Directive” means Directive 2011/24/EU of the European Parliament and of the Council of 9th March 2011 on the application of patients' rights in cross-border healthcare;

“qualifying EEA expenditure” has the same meaning as in section 6BA(3) of the NHS Act 2006 or, as the case may be, of the NHS (Wales) Act;

“service” is to be construed in accordance with section 6BA of the NHS Act 2006 or, as the case may be, the NHS (Wales) Act.

### **Savings provision for cases arising during cross-border arrangements**

**17.—**(1) The legislation referred to in Parts 2 and 3, except for regulations 2, 4(2), 8, 9 and 10, is to continue to apply on and after exit day (and despite any cross-border arrangements ceasing to have effect), without the amendments, repeals and revocations made by those Parts and with the modifications made by Schedule 3, in a case where any of paragraphs (2) to (5) apply.

(2) This paragraph applies where a service that satisfies the condition in section 6BA(4) or (7) of the NHS Act 2006 or the NHS (Wales) Act is provided, or began to be provided, in an EEA State during the relevant period in relation to that State.

(3) This paragraph applies where, during the relevant period in relation to an EEA State, an application under section 6BB of the NHS Act 2006 or the NHS (Wales) Act for authorisation in relation to the provision of a service in that State was made, but not determined.

(4) This paragraph applies where, during the relevant period in relation to an EEA State, authorisation is given under section 6BB of the NHS Act 2006 or the NHS (Wales) Act in relation to the provision of a service in that State.

(5) This paragraph applies where a cross-border healthcare service was provided, or began to be provided, to a visiting patient during the relevant period in relation to the patient's member State of affiliation within the meaning of Article 3(c) of the Directive.

(6) Nothing in this regulation—

(a) requires reimbursement of qualifying EEA expenditure incurred on a service which was provided in an EEA State after the later of—

(i) the end of the period of one year beginning with the day after the end of the relevant period in relation to that State, or

- (ii) in a case where the authorisation for the service authorises the service to be provided within a specified period, the end of the specified period;
  - (b) imposes an obligation in relation to a charge to a visiting patient for a service which was provided after the end of the period of one year beginning with the day after the end of the relevant period in relation to the member State which was the visiting patient's member State of affiliation within the meaning of Article 3(c) of the Directive.
- (7) This regulation does not have effect in a case to which regulation 15 applies.
- (8) In this regulation—
- “cross-border arrangements” is to be construed in accordance with regulation 16;
  - “cross-border healthcare service” and “visiting patient” have the same meaning as in the 2013 Regulations;
  - “the Directive” has the same meaning as in regulation 16;
  - “qualifying EEA expenditure” has the same meaning as in section 6BA(3) of the NHS Act 2006;
  - “the relevant period” means, in relation to an EEA State, the period during which cross-border arrangements between the United Kingdom and that State have effect;
  - “service” is to be construed in accordance with section 6BA of the NHS Act 2006 or, as the case may be, the NHS (Wales) Act.

## PART 6

### **Rights etc deriving from the Treaties**

#### **EU-derived rights**

**18.** Any rights, powers, liabilities, obligations, restrictions, remedies and procedures which continue to be recognised and available in domestic law<sup>(a)</sup> by virtue of section 4 of the European Union (Withdrawal) Act 2018 (including as they are modified by domestic law from time to time) 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.

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

Date

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

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(a) “Domestic law” is defined in section 20 of the European Union (Withdrawal) Act 2018.

## Cross-border cases arising before exit day

## PART 1

## Modifications to primary legislation

**Modifications to the NHS Act 2006**

1. The NHS Act 2006 is to be read as if—
  - (a) in the headings to sections 6A and 6BA (reimbursement of cost of services provided in an EEA state), for references to “another EEA state” there were substituted “an EEA state”;
  - (b) in those sections, for references to “an EEA state other than the United Kingdom” there were substituted “an EEA state”;
  - (c) in section 6D (regulations relating to EU obligations) and the heading to that section, for references to “EU obligations” there were substituted “retained EU obligations”;
  - (d) in section 6E(7)(b) (regulations as to exercise of functions by the Board or clinical commissioning groups), for the reference to “EU obligations” there were substituted “retained EU obligations”;
  - (e) in section 275(1) (interpretation), in the definition of “Regulation (EC) No. 883/2004” 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”.

**Modifications to the NHS (Wales) Act**

2. The NHS (Wales) Act is to be read as if—
  - (a) in the headings to sections 6A and 6BA (reimbursement of cost of services provided in an EEA state), for references to “another EEA state” there were substituted “an EEA state”;
  - (b) in those sections, for references to “an EEA state other than the United Kingdom” there were substituted “an EEA state”;
  - (c) in section 206(1) (interpretation), in the definition of “Regulation (EC) No. 883/2004” 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”.

**Modifications to the Health and Social Care Act 2012**

3. The Health and Social Care Act 2012 is to be read as if—
  - (a) in section 124(9) (local modifications of prices: agreements), for “an EU obligation” there were substituted “a retained EU obligation”;
  - (b) in section 125(9) (local modifications of prices: applications), for “an EU obligation” there were substituted “a retained EU obligation”.

**Modification to the Cities and Local Government Devolution Act 2016**

4. The Cities and Local Government Devolution Act 2016 is to be read as if for section 18(2)(b) (devolving health service functions) there were substituted—
  - “(b) sections 6BA and 6BB of that Act (duties regarding the reimbursement of costs of services provided in an EEA state).”.

## PART 2

### Modifications to secondary legislation

#### Modifications to the 2013 Regulations

5. The 2013 Regulations are to be read as if—
- (a) in regulation 1(3) (interpretation)—
    - (i) in the definition of “resident patient”, for the reference to “the United Kingdom is” there were substituted “immediately before exit day the United Kingdom was”;
    - (ii) in the definition of “visiting patient”, for the reference to “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 regulation 2 (national contact point: designation), for references to “must” there were substituted “may”;
  - (c) in regulation 3 (NCP: information about treatment in England and Wales)—
    - (i) in paragraph (1), before “ensure” there were inserted “make reasonable efforts to”;
    - (ii) in paragraph (2), before “ensure” there were inserted “make reasonable efforts to”;
  - (d) in the heading to regulation 4 (NCP: information about treatment in a member State), for the reference to “another member State” there were substituted “a member State”;
  - (e) in regulation 4(1)—
    - (i) before “ensure” there were inserted “make reasonable efforts to”;
    - (ii) for references to “other member States” there were substituted “member States”;
    - (iii) for the reference to “another member State” there were substituted “a member State”;
  - (f) regulation 4A (NCP: information about prescriptions) were omitted;
  - (g) in regulation 5 (NCP: cross-border co-operation)—
    - (i) for paragraph (1) there were substituted—

“(1) In so far as it considers it is appropriate for the purposes of giving effect to regulation 15 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019, the NCP must make reasonable efforts to co-operate with the national contact points in member States and any other national contact points in the United Kingdom.”;
    - (ii) in paragraph (2), after “must” there were inserted “so far as the NCP considers appropriate”;
  - (h) regulation 6 (NCP: duty to consult) were omitted;
  - (i) in regulation 9(1) (information on rights and entitlements), after “must” there were inserted “make reasonable efforts to”;
  - (j) in regulation 12(1) (information on rights and entitlements), after “must” there were inserted “make reasonable efforts to”;
  - (k) in the heading to regulation 14 (exemption from NHS charges), for the reference to “another member State” there were substituted “a member State”;
  - (l) in regulation 14—
    - (i) in paragraph (2), for the reference to “P is” there were substituted “immediately before exit day P was”;
    - (ii) in paragraph (2)(a), for the reference to “is resident” there were substituted “was resident”;
    - (iii) in paragraph (2)(b), for the reference to “is the competent member State” there were substituted “was the competent member State”;

- (iv) in paragraph (3)(b), after the reference to “it is not provided” there were inserted “or, had it been provided immediately before exit day, it would not be provided”;
- (v) 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 regulation 16 (review), after paragraph (5) there were inserted—  
“(6) No review may be carried out after 31 December 2020.”
- (n) the Schedule (elements that must be included in prescriptions) were omitted.

**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, in regulation 3(a) (exercise of functions), for references to “another EEA state” there were substituted “an EEA state”.

**SCHEDULE 2**

Regulation 16

**Cases arising during cross-border arrangements**

**PART 1**

**Modifications to primary legislation**

**Modifications to the NHS Act 2006**

1. The NHS Act 2006 is to be read as if—
  - (a) sections 6A (reimbursement of cost of services provided in another EEA State) and 6B (prior authorisation for the purposes of section 6A) were omitted;
  - (b) in the heading to section 6BA (reimbursement of cost of services provided in another EEA state), for the reference to “another EEA state” there were substituted “an EEA state”;
  - (c) in section 6BA(3), for the reference to “an EEA state other than the United Kingdom” there were substituted “an EEA state”;
  - (d) for section 6BA(15) there were substituted—  
“(15) In this section and section 6BB—  
“authorised provider” in relation to any service provided in an EEA state means a person who is lawfully providing that service;  
“NHS charge” means a charge payable under regulations made under section 172(1), 176(1) or 179(1);  
“responsible authority” means, in relation to a patient, a local authority or clinical commissioning group responsible under or by virtue of this Act for providing or arranging for the provision of services for the benefit of the patient;  
“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.”;
  - (e) in section 6D (regulations relating to EU obligations) and the heading to that section, for references to “EU obligations” there were substituted “retained EU obligations”;
  - (f) in section 6E(7)(b) (regulations as to exercise of functions by the Board or clinical commissioning groups), for the reference to “EU obligations” there were substituted “retained EU obligations”;

- (g) in section 183(a)(ii) (payment of travelling expenses) for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
- (h) in section 275(1) (interpretation), in the definition of “Regulation (EC) No. 883/2004” 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”.

### **Modifications to the NHS (Wales) Act**

2. The NHS (Wales) Act is to be read as if—

- (a) sections 6A (reimbursement of cost of services provided in another EEA State) and 6B (prior authorisation for the purposes of section 6A) were omitted;
- (b) in the heading to section 6BA (reimbursement of cost of services provided in another EEA state), for the reference to “another EEA state” there were substituted “an EEA state”;
- (c) in section 6BA(3), for the reference to “an EEA state other than the United Kingdom” there were substituted “an EEA state”;
- (d) for section 6BA(15) there were substituted—
  - “(15) In this section and section 6BB—
    - “authorised provider”, in relation to any service provided in an EEA state, means a person who is lawfully providing that service;
    - “NHS charge” means a charge payable under regulations made under section 121(1), 125(1) or 128(1);
    - “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.”;
- (e) in section 131(a)(ii) (payment of travelling expenses) for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
- (f) in section 206(1) (interpretation), in the definition of “Regulation (EC) No. 883/2004” 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”.

### **Modifications to the Health and Social Care Act 2012**

3. The Health and Social Care Act 2012 is to be read as if—

- (a) in section 124(9) (local modifications of prices: agreements), for “an EU obligation” there were substituted “a retained EU obligation”;
- (b) in section 125(9) (local modifications of prices: applications), for “an EU obligation” there were substituted “a retained EU obligation”.

### **Modification to the Cities and Local Government Devolution Act 2016**

4. The Cities and Local Government Devolution Act 2016 is to be read as if for section 18(2)(b) (devolving health service functions) there were substituted—

- “(b) sections 6BA and 6BB of that Act (duties regarding the reimbursement of costs of services provided in an EEA state).”.

## PART 2

### Modifications to secondary legislation

#### **Modifications to the Welsh Ambulance Services National Health Service Trust (Establishment) Order 1998**

5. The Welsh Ambulance Services National Health Service Trust (Establishment) Order 1998 is to be read as if—

- (a) in article 1(2) (interpretation)—
  - (i) the definition of “Directive 2011/24/EU” were omitted;
  - (ii) for the definition of “National Contact Point” there were substituted—

““National Contact Point” means the National Contact Point that may be designated in relation to Wales under regulation 2 of the National Health Service (Cross-Border Healthcare) Regulations 2013;”
- (b) in article 3(2)(d) (nature and functions of the trust), the reference to “for the purposes of Directive 2011/24/EU” were omitted.

#### **Modifications to the 2013 Regulations**

6. The 2013 Regulations are to be read as if—

- (a) in regulation 1(3) (interpretation)—
  - (i) after the definition of “clinical commissioning group” there were inserted—

““cross-border arrangements” is to be construed in accordance with regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019;”
  - (ii) in the definition of “healthcare provider” for “member State” there were substituted “relevant member State”;
  - (iii) 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)(a) of the Human Medicines Regulations 2012(b) in a member State that is included in that list in relation to that profession;”
  - (iv) after the definition of “prescription” there were inserted—

““relevant member State” means a member State which is included in a list maintained under regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019;”;
  - (v) for the definition of “resident patient” there were substituted—

““resident patient” means an individual who is ordinarily resident in England or Wales;”;
  - (vi) in the definition of ““visiting patient” for “a member State other than the United Kingdom” there were substituted “a relevant member State””;
- (b) in regulation 2 (national contact point: designation)—
  - (i) for references to “must” there were substituted “may”;
  - (ii) for references to “the Directive” there were substituted “cross-border arrangements”;
- (c) in regulation 3 (NCP: information about treatment in England and Wales)—

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

(b) S.I. 2012/1916.

- (i) in paragraph (1), before “ensure” there were inserted “make reasonable efforts to”;
- (ii) in paragraph (2), before “ensure” there were inserted “make reasonable efforts to”;
- (d) in the heading to regulation 4 (NCP: information about treatment in a member State), for the reference to “another member State” there were substituted “a relevant member State”;
- (e) in regulation 4(1)—
  - (i) for references to “other member States” there were substituted “relevant member States”;
  - (ii) before “ensure” there were inserted “make reasonable efforts to”;
  - (iii) for the reference to “another member State” there were substituted “a relevant member State”;
- (f) in the heading to regulation 4A (NCP: information about prescriptions), for the reference to “another member State” there were substituted “the United Kingdom”;
- (g) for regulation 4A there were substituted—
 

“(4A) The NCP must make reasonable efforts to make available to patients information about the elements, specified in the Schedule, to be included in a prescription which is—

  - (a) issued in a member State included in the list published under regulation 214(6A) of the Human Medicines Regulations 2012<sup>(a)</sup>, and
  - (b) intended to be used in the United Kingdom.”;
- (h) in regulation 5 (NCP: cross-border co-operation) —
  - (i) for paragraph (1) 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 make reasonable efforts to co-operate with the national contact points in relevant member States and any other national contact points in the United Kingdom.”;
  - (ii) in paragraph (2), after “must” there were inserted “so far as the NCP considers appropriate”;
- (i) in regulation 6 (NCP: duty to consult), for the words from “the Directive”, in the first place, to “in these Regulations”, there were substituted “cross-border arrangements”;
- (j) for regulation 9(1) (information on rights and entitlements) there were substituted—
 

“(1) The Board or a clinical commissioning group must make reasonable efforts to ensure that information on their rights and entitlements under sections 6BA and 6BB of the NHS Act is provided to resident patients for whom the Board or the clinical commissioning group is responsible for making services available under that Act.”;
- (k) for regulation 12(1) (information on rights and entitlements) there were substituted—
 

“(1) A Local Health Board must make reasonable efforts to ensure that information on their rights and entitlements under sections 6BA and 6BB of the NHS (Wales) Act is provided to resident patients for whom it is responsible for making services available under that Act.”;
- (l) in regulation 13(2) (NHS charges)—
  - (i) in paragraph (a) of the definition of “cross-border healthcare service”, for the reference to “that patient exercising their rights in relation to access to healthcare under the Directive” there were substituted “cross-border arrangements”;
  - (ii) in the definition of “responsible authority”, for the reference to “section 6A(11)” there were substituted “section 6BA(15)”;

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<sup>(a)</sup> Paragraph (6A) of regulation 214 is inserted by the Human Medicines (Amendment etc.)(EU Exit) Regulations 2019.

- (m) in the heading to regulation 14 (exemption from NHS charges), for the reference to “another member State” there were substituted “a relevant member State”;
- (n) in regulation 14—
  - (i) in paragraph (2)(a), for the reference to “a member State other than the United Kingdom” there were substituted “a relevant member State”;
  - (ii) in paragraph (3)(b), after the reference to “it is not provided” there were inserted “or, had it been provided immediately before exit day, it would not be provided”;
  - (iii) 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”;
- (o) in regulation 16 (review), after paragraph (5) there were inserted—
 

“(6) No review may be carried out after 31 December 2020.”;
- (p) in the heading to the Schedule (elements that must be included in prescriptions)(a) for the reference to “ANOTHER MEMBER STATE” there were substituted “THE UNITED KINGDOM”;
- (q) 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), the reference to “as defined in Article 1 of Directive 2001/83/EC” were omitted.

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

**7. The NHS Functions Regulations are to be read as if—**

- (a) in regulation 3(a) (exercise of functions)—
  - (i) the reference to “sections 6A and 6B of the 2006 Act (prior authorisation of and reimbursement of costs of services provided in another EEA state) or” were omitted;
  - (ii) for the second reference to “another EEA state” there were substituted “an EEA state”;
- (b) in regulation 4 (procedure for applications)—
  - (i) in paragraph (1)(a), for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
  - (ii) in paragraph (1)(b), for the reference to “section 6B or 6BB” there were substituted “section 6BB”;
  - (iii) in paragraph (3)(a) for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
  - (iv) in that paragraph, for the reference to “section 6B or 6BB” there were substituted “section 6BB”;
- (c) in regulation 6 (form and content of determination)—
  - (i) in paragraph (2)(a), for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
  - (ii) in paragraph (2)(b), for the reference to “section 6B or 6BB” there were substituted “section 6BB”;

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(a) The Schedule was inserted by S.I. 2015/139.

- (d) in regulation 7(3)(a) (CCGs), for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
- (e) regulation 8 (applications made before 1st April 2013) were omitted.

## SCHEDULE 3

Regulation 17

### Savings provision for cases arising during cross-border arrangements

#### PART 1

##### Modifications to primary legislation

###### **Modifications to the NHS Act 2006**

1. The NHS Act 2006 is to be read as if—
  - (a) sections 6A (reimbursement of cost of services provided in an EEA State) and 6B (prior authorisation for the purposes of section 6A) were omitted;
  - (b) in the heading to section 6BA (reimbursement of cost of services provided in an EEA state), for the reference to “another EEA state” there were substituted “an EEA state”;
  - (c) in section 6BA(3), for the reference to “an EEA state other than the United Kingdom” there were substituted “an EEA state”;
  - (d) for section 6BA(15) there were substituted—
 

“(15) In this section and section 6BB—

“authorised provider” in relation to any service provided in an EEA state means a person who is lawfully providing that service;

“NHS charge” means a charge payable under regulations made under section 172(1), 176(1) or 179(1);

“responsible authority” means, in relation to a patient, a local authority or clinical commissioning group responsible under or by virtue of this Act for providing or arranging for the provision of services for the benefit of the patient;

“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.”;
  - (e) in section 6D (regulations relating to EU obligations) and the heading to that section, for references to “EU obligations” there were substituted “retained EU obligations”;
  - (f) in section 6E(7)(b) (regulations as to exercise of functions by the Board or clinical commissioning groups), for the reference to “EU obligations” there were substituted “retained EU obligations”;
  - (g) in section 183(a)(ii) (payment of travelling expenses) for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
  - (h) in section 275(1) (interpretation), in the definition of “Regulation (EC) No. 883/2004” 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”.

###### **Modifications to the NHS (Wales) Act**

2. The NHS (Wales) Act is to be read as if—

- (a) sections 6A (reimbursement of cost of services provided in an EEA State) and 6B (prior authorisation for the purposes of section 6A) were omitted;
- (b) in the heading to section 6BA (reimbursement of cost of services provided in an EEA state), for the reference to “another EEA state” there were substituted “an EEA state”;
- (c) in section 6BA(3), for the reference to “an EEA state other than the United Kingdom” there were substituted “an EEA state”;
- (d) for section 6BA(15) there were substituted—
  - “(15) In this section and section 6BB—
    - “authorised provider”, in relation to any service provided in an EEA state, means a person who is lawfully providing that service;
    - “NHS charge” means a charge payable under regulations made under section 121(1), 125(1) or 128(1);
    - “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.”;
- (e) in section 131(a)(ii) (payment of travelling expenses) for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
- (f) in section 206(1) (interpretation), in the definition of “Regulation (EC) No. 883/2004” 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”.

### **Modifications to the Health and Social Care Act 2012**

- 3. The Health and Social Care Act 2012 is to be read as if—
  - (a) in section 124(9) (local modifications of prices: agreements), for “an EU obligation” there were substituted “a retained EU obligation”;
  - (b) in section 125(9) (local modifications of prices: applications), for “an EU obligation” there were substituted “a retained EU obligation”.

### **Modification to the Cities and Local Government Devolution Act 2016**

- 4. The Cities and Local Government Devolution Act 2016 is to be read as if for section 18(2)(b) (devolving health service functions) there were substituted—
  - “(b) sections 6BA and 6BB of that Act (duties regarding the reimbursement of costs of services provided in an EEA state).”.

## **PART 2**

### **Modifications to secondary legislation**

### **Modifications to the Welsh Ambulance Services National Health Service Trust (Establishment) Order 1998**

- 5. The Welsh Ambulance Services National Health Service Trust (Establishment) Order 1998 is to be read as if—
  - (a) in article 1(2) (interpretation)—
    - (i) the definition of “Directive 2011/24/EU” were omitted;
    - (ii) for the definition of “National Contact Point” there were substituted—

“National Contact Point” means the National Contact Point that may be designated in relation to Wales under regulation 2 of the National Health Service (Cross-Border Healthcare) Regulations 2013”;

- (b) in article 3(2)(d) (nature and functions of the trust), the reference to “for the purposes of Directive 2011/24/EU” were omitted.

## **Modifications to the 2013 Regulations**

### **6. The 2013 Regulations are to be read as if—**

- (a) in regulation 1(3) (interpretation)—
- (i) after the definition of “clinical commissioning group” there were inserted—
- “cross-border arrangements” is to be construed in accordance with regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019”;
- (ii) in the definition of “healthcare provider” for “member State” there were substituted “relevant member State”;
- (iii) 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)(a) of the Human Medicines Regulations 2012(b) in a member State that is included in that list in relation to that profession”;
- (iv) after the definition of “prescription” there were inserted—
- “relevant member State” means a member State which is included in a list maintained under regulation 16 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019;
- “the relevant period” in relation to a member State, has the same meaning as in regulation 17 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019”;
- (v) for the definition of “resident patient”, there were substituted—
- “resident patient” means an individual who is ordinarily resident in England or Wales”;
- (vi) for the definition of “visiting patient”, there were substituted—
- “visiting patient” means an individual for whom a relevant member State was the member State of affiliation within the meaning of Article 3(c) of the Directive during the relevant period in relation to that State”;
- (b) in regulation 2 (national contact point: designation)—
- (i) for references to “must” there were substituted “may”;
- (ii) for references to “the Directive” there were substituted “cross-border arrangements”;
- (c) in regulation 3 (NCP: information about treatment in England and Wales)—
- (i) in paragraph (1), before “ensure” there were inserted “make reasonable efforts to”;
- (ii) in paragraph (2), before “ensure” there were inserted “make reasonable efforts to”;
- (d) in the heading to regulation 4 (NCP: information about treatment in a member State), for the reference to “another member State” there were substituted “a relevant member State”;
- (e) in regulation 4(1)—

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(a) Paragraph (6A) of regulation 214 is inserted by the Human Medicines (Amendment etc.)(EU Exit) Regulations 2019.

(b) S.I. 2012/1916.

- (i) for references to “other member States” there were substituted “relevant member States”;
- (ii) before “ensure” there were inserted “make reasonable efforts to”;
- (iii) for the reference to “another member State” there were substituted “a relevant member State”;
- (f) regulation 4A (NCP: information about prescriptions) were omitted;
- (g) in regulation 5(1) (NCP: cross-border co-operation)—
  - (i) for paragraph (1) there were substituted—
 

“(1) In so far as it considers it is appropriate for the purposes of giving effect to regulation 17 of the National Health Service (Cross-Border Healthcare and Miscellaneous Amendments etc) (EU Exit) Regulations 2019, the NCP must make reasonable efforts to co-operate with the national contact points in relevant member States and any other national contact points in the United Kingdom.”;
  - (ii) in paragraph (2), after “must” there were inserted “so far as the NCP considers appropriate”;
- (h) regulation 6 (NCP: duty to consult) were omitted;
- (i) for regulation 9(1) (information on rights and entitlements) there were substituted—
 

“(1) The Board or a clinical commissioning group must make reasonable efforts to ensure that information on their rights and entitlements under sections 6BA and 6BB of the NHS Act is provided to resident patients for whom the Board or the clinical commissioning group is responsible for making services available under that Act.”;
- (j) for regulation 12(1) (information on rights and entitlements) there were substituted—
 

“(1) A Local Health Board must make reasonable efforts to ensure that information on their rights and entitlements under sections 6BA and 6BB of the NHS (Wales) Act is provided to resident patients for whom it is responsible for making services available under that Act.”;
- (k) in regulation 13(2) (NHS charges)—
  - (i) in paragraph (a) of the definition of “cross-border healthcare service”, for the reference to “that patient exercising their rights in relation to access to healthcare under the Directive” there were substituted “cross-border arrangements”;
  - (ii) in the definition of “responsible authority”, for the reference to “section 6A(11)” there were substituted “section 6BA(15)”;
- (l) in the heading to regulation 14 (exemption from NHS charges), for the reference to “another member State” there were substituted “a relevant member State”;
- (m) in regulation 14—
  - (i) in paragraph (2)(a), for the reference to “a member State other than the United Kingdom” there were substituted “a relevant member State”;
  - (ii) in paragraph (3)(b), after the reference to “it is not provided” there were inserted “or, had it been provided immediately before exit day, it would not be provided”;
  - (iii) 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”;
- (n) in regulation 16 (review), after paragraph (5) there were inserted—
 

“(6) No review may be carried out after 31 December 2020.”;
- (o) the Schedule (elements that must be included in prescriptions)(a) were omitted.

---

(a) The Schedule was inserted by S.I. 2015/139.

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

7. The NHS Functions Regulations are to be read as if—

- (a) in regulation 3(a) (exercise of functions)—
  - (i) the reference to “sections 6A and 6B of the 2006 Act (prior authorisation of and reimbursement of costs of services provided in another EEA state) or” were omitted;
  - (ii) for the second reference to “another EEA state” there were substituted “an EEA state”;
- (b) in regulation 4 (procedure for applications)—
  - (i) in paragraph (1)(a), for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
  - (ii) in paragraph (1)(b), for the reference to “section 6B or 6BB” there were substituted “section 6BB”;
  - (iii) in paragraph (3)(a), for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
  - (iv) in that paragraph, for the reference to “section 6B or 6BB” there were substituted “section 6BB”;
- (c) in regulation 6 (form and content of determination)—
  - (i) in paragraph (2)(a), for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
  - (ii) in paragraph (2)(b), for the reference to “section 6B or 6BB” there were substituted “section 6BB”;
- (d) in regulation 7(3)(a) (CCGs), for the reference to “section 6A or 6BA” there were substituted “section 6BA”;
- (e) regulation 8 (applications made before 1st April 2013) were omitted.

### EXPLANATORY NOTE

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

These Regulations are made in exercise of the powers in section 8 of the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c), (d), (e) and (g)) arising from the withdrawal of the United Kingdom from the European Union.

Part 2 amends primary legislation, Part 3 amends secondary legislation, Part 4 revokes retained direct EU legislation, Part 5 contains savings and transitional provisions and Part 6 relates to rights and other matters which become part of domestic law by virtue of section 4 of the European Union (Withdrawal) Act 2018.

An impact assessment has been prepared in relation to these Regulations and copies can be obtained from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

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£6.90

UK201902071019 02/2019 19585

<http://www.legislation.gov.uk/id/ukdsi/2019/9780111180709>

ISBN 978-0-11-118070-9



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