### 2019 No. 1293

# **EXITING THE EUROPEAN UNION**

## **HEALTH SERVICES**

# NATIONAL HEALTH SERVICE, ENGLAND AND WALES

# NATIONAL HEALTH SERVICE, SCOTLAND

# HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

The Healthcare (European Economic Area and Switzerland Arrangements) (EU Exit) Regulations 2019

Made - - - - 2nd October 2019
Laid before Parliament 3rd October 2019

Coming into force in accordance with regulation 1(2)

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 2(1) and (2)(b), (f) and (h) and 7(2) of the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019(a).

In accordance with section 5(1) of that Act, the Secretary of State has consulted the Scottish Ministers, the Welsh Ministers and the Department of Health in Northern Ireland before making these Regulations.

## Citation, commencement and interpretation

- **1.**—(1) These Regulations may be cited as the Healthcare (European Economic Area and Switzerland Arrangements) (EU Exit) Regulations 2019.
  - (2) These Regulations come into force on exit day(b).
  - (3) In these Regulations—

<sup>(</sup>a) 2019 c. 14 ("the 2019 Act").

<sup>(</sup>b) "Exit day" is defined by Schedule 1 to the Interpretation Act 1978 (c. 30) ("the 1978 Act").

"the Authority" means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established under article 2 of the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(a);

"enactment" includes-

- (a) an enactment comprised in, or in an instrument made under, primary legislation(b); and
- (b) any retained direct EU legislation(c);

"health service body" means—

- (a) an NHS body as defined in section 275 of the National Health Service Act 2006(d) (interpretation) or in section 206 of the National Health Service (Wales) Act 2006(e) (interpretation);
- (b) a body listed in section 17A(2)(a) to (c) or (e) of the National Health Service (Scotland) Act 1978(f) (NHS contracts) or in article 8(2)(a) to (d) of the Health and Personal Social Services (Northern Ireland) Order 1991(g) (health and social care contracts); or
- (c) a provider of healthcare(h) who is a public authority(i) (not falling within sub-paragraph (a) or (b));

"healthcare arrangement" means—

- (a) a healthcare agreement(j); or
- (b) an arrangement, other than a healthcare agreement, made by the Secretary of State, for or in connection with the provision of healthcare in a member state;

"listed healthcare arrangement" means a healthcare arrangement included in the list maintained in accordance with regulation 8;

"maternity application" means an application for authorisation to travel to a member state (or another member state) for the purpose of receiving healthcare in connection with giving birth in that member state;

"member state" means an EEA state or Switzerland;

"relevant health board" means—

- (a) in relation to England and in relation to relevant persons, the National Health Service Commissioning Board established under section 1H of the National Health Service Act 2006(k);
- (b) in relation to Wales, a Local Health Board established under section 11 of the National Health Service (Wales) Act 2006;
- (c) in relation to Scotland, a Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978(I);

(b) See section 7(6) of the 2019 Act as to the meaning of "primary legislation".

- (h) See section 3 of the 2019 Act as to the meaning of "healthcare".
- (i) See section 2 of the 2019 Act as to the meaning of "public authority".
- (j) See section 3 of the 2019 Act as to the meaning of "healthcare agreement".
- (k) Section 1H was inserted by the 2012 Act, section 9. Transitory modifications are made by S.I. 2012/1831.
- (1) Section 2 was amended by: the Health and Social Services and Social Security Adjudications Act 1983 (c. 41), Schedule 7, paragraph 1; the National Health Service and Community Care Act 1990 (c. 19), section 28, Schedule 9, paragraph 19(1), and Schedule 10; the National Health Service Reform (Scotland) Act 2004 (asp 7), Schedule 1, paragraph 1(2); the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), Schedule 2, paragraph 2(2); and the Health Boards (Membership and Elections) (Scotland) Act 2009 (asp 5), section 2(1).

<sup>(</sup>a) S.I. 2005/2414.

<sup>(</sup>c) "Retained direct EU legislation" is defined by Schedule 1 to the 1978 Act.

<sup>(</sup>d) 2006 c. 41. The definition was inserted by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), Schedule 4, paragraph 138. (e) 2006 c. 42. The definition was inserted by the 2012 Act, Schedule 21, paragraph 38.

<sup>(</sup>f) 1978 c. 29. Section 17A was inserted by the National Health Service and Community Care Act 1990 (c. 19), section 30, and amended by: the Health Act 1999 (c. 8), Schedule 4, paragraph 46 and Schedule 5, paragraph 1; the Health and Social Care (Community Health and Standards) Act 2003 (c. 43), Schedule 14, paragraph 1; the Public Services Reform (Scotland) Act 2010 (asp 8), Schedule 17, paragraph 8; and the 2012 Act, Schedule 21, paragraph 2.

<sup>(</sup>g) S.I. 1991/194 (N.I. 1). Relevant amendments were made by the Health and Social Care (Reform) Act (Northern Ireland) 2009 (c. 1), Schedule 6, paragraphs 1 and 13.

(d) in relation to Northern Ireland, the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009(a); and

"relevant person" means a person residing in a member state needing authorisation from the United Kingdom to travel to another member state for the purpose of receiving healthcare under a healthcare arrangement.

#### Functions relating to healthcare payments and assisting the Secretary of State

- **2.** Subject to, and in accordance with, such instructions as the Secretary of State may give, the Authority must—
  - (a) make payments under section 1 of the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 (power to make healthcare payments); and
  - (b) assist the Secretary of State in relation to the Secretary of State's exercise of—
    - (i) functions under that section;
    - (ii) functions in giving effect to healthcare arrangements; and
    - (iii) functions otherwise in connection with the provision of healthcare in a member state.

#### Functions relating to transitional reciprocal arrangements

- **3.**—(1) The Authority must give effect to the obligations of the United Kingdom under the relevant retained direct EU legislation.
- (2) The duty in paragraph (1) includes (but is not limited to) doing the following in accordance with the relevant retained direct EU legislation—
  - (a) processing and determining any applications or claims, including any maternity applications;
  - (b) registering any entitlements;
  - (c) making any payments; and
  - (d) issuing any documents verifying entitlement to the provision of healthcare.
- (3) But the duty in paragraph (1) does not include a duty to give effect to the obligations of the United Kingdom under the relevant retained direct EU legislation to the extent that—
  - (a) doing so involves the exercise of the function of a relevant health board in determining an application (other than a maternity application) for the purposes of giving effect to Article 20 or 27 of Regulation (EC) No 883/2004 (authorisation for healthcare in a member state); or
  - (b) the Secretary of State or another person is under a duty to give, is due to give, or has given, effect to those obligations.
- (4) The Secretary of State may give effect to the relevant retained direct EU legislation, and that power includes (but is not limited to) a power to do the things mentioned in paragraph (2)(a) to (d).
- (5) But the power in paragraph (4) does not include a power to give effect to the relevant retained direct EU legislation to the extent that doing so involves the exercise of a function exercisable by a devolved authority(**b**) under any enactment.
  - (6) In this regulation—

"Regulation (EEC) No 1408/71" means Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community;

<sup>(</sup>a) 2009 c. 1 (N.I.).

**<sup>(</sup>b)** See section 5 of the 2019 Act as to the meaning of "devolved authority".

"Regulation (EEC) No 574/72" means Council Regulation (EEC) No 574/72 of 21 March 1972 laying down the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to their families moving within the Community;

"Regulation (EC) No 859/2003" means Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality;

"Regulation (EC) No 883/2004" means Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems;

"Regulation (EC) No 987/2009" means Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems;

"relevant benefits in kind"—

- (a) in relation to Regulation (EC) No 883/2004, means the benefits in kind referred to in Article 1(va)(i) and (ii) of that Regulation;
- (b) in relation to Regulation (EEC) No 1408/71, means the benefits in kind to which Chapter 1 or 4 of Title 3 of that Regulation applies immediately before exit day; and

"the relevant retained direct EU legislation" means—

- (a) Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009, and
- (b) Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 (as extended by Regulation (EC) No 859/2003),

so far as relating to the coordination of the provision of relevant benefits in kind, and as continued by regulation 17 of, and Schedule 5 to, the Social Security Coordination (Reciprocal Healthcare) (Amendment etc.) (EU Exit) Regulations 2019(a) (savings and transitional provision).

#### **Functions relating to healthcare arrangements**

- **4.**—(1) The Authority must give effect to the obligations and commitments of the United Kingdom under any listed healthcare arrangements.
- (2) The duty in paragraph (1) includes (but is not limited to) doing the following in accordance with any listed healthcare arrangements—
  - (a) processing and determining any applications or claims, including any maternity applications;
  - (b) registering any entitlements;
  - (c) making any payments; and
  - (d) issuing any documents verifying entitlement to the provision of healthcare.
- (3) But the duty in paragraph (1) does not include a duty to give effect to the obligations and commitments of the United Kingdom under a listed healthcare arrangement to the extent that—
  - (a) doing so involves the discharge of the duty of a relevant health board under regulation 6(1); or
  - (b) the Secretary of State or another person is under a duty to give, is due to give, or has given, effect to those obligations or commitments.
- (4) The Secretary of State may give effect to any listed healthcare arrangements, and that power includes (but is not limited to) a power to do the things mentioned in paragraph (2)(a) to (d).

<sup>(</sup>a) S.I. 2019/776.

(5) But the power in paragraph (4) does not include a power to give effect to a listed healthcare arrangement to the extent that doing so involves the exercise of a function exercisable by a devolved authority under regulation 6(3) or another enactment.

#### Functions relating to information and advice

- **5.**—(1) The Authority must establish and maintain a service making available to the public information and advice in relation to—
  - (a) its functions under these Regulations;
  - (b) the provision of healthcare under healthcare arrangements; and
  - (c) any evidential or administrative requirements or processes under those arrangements.
- (2) The service referred to in paragraph (1) may include information and advice in relation to such other matters relating to healthcare arrangements or in connection with the provision of healthcare in a member state as the Authority considers appropriate.

#### Functions relating to authorisation for planned healthcare

- **6.**—(1) Relevant health boards must determine planned healthcare applications, and must do so in accordance with any listed healthcare arrangements.
- (2) But the duty in paragraph (1) does not include a duty to determine a planned healthcare application to the extent that the application—
  - (a) is a maternity application; or
  - (b) is due to be, or has been, determined under paragraph (3).
  - (3) Planned healthcare applications may be determined—
    - (a) in relation to England and in relation to relevant persons, by the Secretary of State;
    - (b) in relation to Wales, by the Welsh Ministers;
    - (c) in relation to Scotland, by the Scottish Ministers; and
    - (d) in relation to Northern Ireland, by the Department of Health in Northern Ireland.
- (4) In this regulation, "planned healthcare application" means an application for authorisation to travel to a member state (or another member state) for the purpose of receiving healthcare under a listed healthcare arrangement.

#### Duty to act in accordance with healthcare arrangements

7. Health service bodies must, when exercising functions and insofar as not already required by regulation 4 or 6, act in accordance with any listed healthcare arrangements.

#### List of healthcare arrangements

- **8.**—(1) The Secretary of State must maintain a list for the purposes of regulations 4 to 7 and 9.
- (2) The list must specify in relation to each healthcare arrangement included in the list—
  - (a) when the healthcare arrangement is to be treated as beginning to have effect; and
  - (b) when the healthcare arrangement is to be treated as ceasing to have effect.
- (3) The Secretary of State may specify different times under paragraph (2)(a) or (b) in relation to different parts of a healthcare arrangement.
- (4) The Secretary of State may remove a healthcare arrangement from the list before the time specified in the list as the time when the arrangement is to be treated as beginning to have effect.
- (5) The Secretary of State may change a time specified in the list (but not after the time specified).
  - (6) The Secretary of State must publish the list and keep it up to date.

#### **Transitional provision**

- **9.**—(1) This paragraph applies where a listed healthcare arrangement makes provision as to rights, obligations or liabilities acquired, accrued or incurred under the arrangement before the arrangement end time.
- (2) Where paragraph (1) applies, the relevant public body must after the arrangement end time give effect to the provision referred to in that paragraph.
  - (3) This paragraph applies where—
    - (a) paragraph (1) does not apply; and
    - (b) before the arrangement end time of a listed healthcare arrangement, under the arrangement—
      - (i) healthcare was provided, or began to be provided,
      - (ii) authorisation for the provision of healthcare was given, or
      - (iii) an application for authorisation to travel to a member state (or another member state) for the purpose of receiving healthcare was made and such authorisation was not given or refused.
- (4) Where paragraph (3) applies, the relevant public body must after the arrangement end time treat the obligations and commitments of the United Kingdom under the healthcare arrangement as continuing to apply in relation to the matters referred to in paragraph (3)(b)(i) to (iii).
  - (5) Nothing in paragraph (4) requires—
    - (a) healthcare to be provided in the United Kingdom after the later of—
      - (i) the end of the period of one year beginning with the day after the arrangement end time, or
      - (ii) in a case where authorisation under a listed healthcare arrangement has been given for the provision of healthcare in the United Kingdom within a specified period, the end of the specified period; or
    - (b) reimbursement to be made to a member state or a person in respect of healthcare provided after the later of—
      - (i) the end of the period of one year beginning with the day after the arrangement end time, or
      - (ii) in a case where authorisation under a listed healthcare arrangement has been given to travel to a member state (or another member state) for the purpose of receiving healthcare within a specified period, the end of the specified period.
  - (6) In this regulation—

"the arrangement end time" means, in relation to a listed healthcare arrangement, the time when the arrangement is treated as ceasing to have effect in accordance with regulation 8(2)(b); and

"the relevant public body" means—

- (a) in relation to the functions of the Authority under regulation 4, the Authority;
- (b) in relation to the functions of relevant health boards under regulation 6, relevant health boards:
- (c) in relation to the exercise of functions by health service bodies in accordance with listed healthcare arrangements under regulation 7, health service bodies.

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

Edward Argar
Minister of State
Department of Health and Social Care

2nd October 2019

#### EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations confer functions in relation to the provision of healthcare in EEA states and Switzerland ("member states"), including the making of payments in respect of such healthcare, as provided for by the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 (c. 14) ("the 2019 Act"). These Regulations also make provision to give effect to agreements and arrangements relating to the provision of such healthcare ("healthcare arrangements") and for related purposes.

Regulation 2 confers a duty on the NHS Business Services Authority ("the Authority"), subject to instructions given by the Secretary of State, to make payments under section 1 of the 2019 Act, and to assist the Secretary of State with the exercise of the Secretary of State's functions in relation to making such payments, giving effect to healthcare arrangements and the provision of healthcare in member states.

Regulation 3 confers functions on the Authority and the Secretary of State for the purposes of giving effect to EU regulations (within the meaning of Article 288 of the Treaty on the Functioning of the European Union) relating to the provision of reciprocal healthcare. Those EU regulations were converted into domestic law by section 3 of the European Union (Withdrawal) Act 2018 (c. 16). They are continued with modifications, for certain purposes, by the Social Security Coordination (Reciprocal Healthcare) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/776), which were made under section 8 of that Act. The functions of the Authority and the Secretary of State under regulation 3 are subject to exceptions as set out in paragraphs (3) and (5).

Regulation 4 confers functions on the Authority and the Secretary of State for the purposes of giving effect to other healthcare arrangements which are included in a list maintained by the Secretary of State under regulation 8. The functions of the Authority and the Secretary of State are subject to exceptions as set out in paragraphs (3) and (5), including the determination of certain applications relating to planned treatment in member states.

Regulation 5 requires the Authority to establish an information and advice service.

Regulation 6 requires certain health boards in England, Wales, Scotland and Northern Ireland to determine applications relating to planned treatment in member states under healthcare arrangements, save for applications to give birth in a member state which fall to the Authority under regulation 4. Paragraph (3) enables the Secretary of State, the Scottish Ministers, the Welsh Ministers and the Department of Health in Northern Ireland to also determine applications relating to planned treatment.

Regulation 7 requires National Health Service bodies, certain health and social care bodies in Northern Ireland, and other providers of health services to exercise functions in accordance with healthcare arrangements.

Regulation 8 requires the Secretary of State to maintain and publish a list of healthcare arrangements for the purposes of these Regulations.

Regulation 9 makes transitional provision in relation to the end of healthcare arrangements.

An impact assessment has not been prepared for these Regulations. An assessment of the impact of the healthcare arrangements for whose implementation these Regulations provide will be carried out as appropriate and any such assessment will be available from the Department of Health and Social Care at 39 Victoria Street, London, SW1H 0EU.

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