2020 No. 885

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Coronavirus) (Charges and Further Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020

Made - - - - 20th August 2020

Laid before Parliament 24th August 2020

Coming into force in accordance with regulation 1(2)

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 101, 104(1), (2)(a) and (d) and (3), 109(1) and (3)(f), 115, 121(1) and (2)(a) and (d) and (3)(a), 126(2), 128A(1) and (2)(c) and (d), 129(2)(a) and (6), 172(1), 176(1) and (2)(d) and (f), 177(5), 178, 179(1), 180, 182 and 272(7) and (8) of the National Health Service Act 2006(a).

Citation and commencement

- **1.**—(1) These Regulations may be cited as the National Health Service (Coronavirus) (Charges and Further Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020.
- (2) These Regulations come into force on the twenty-first day after the day on which they are laid before Parliament.

Amendment of the National Health Service (Charges for Drugs and Appliances) Regulations 2015

- **2.**—(1) The National Health Service (Charges for Drugs and Appliances) Regulations 2015(b) are amended as follows.
 - (2) After regulation 10 insert—

(b) S.I. 2015/570.

⁽a) 2006 c.41. Section 104 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), Schedule 4, paragraph 46. Section 109 has been amended by the 2012 Act, Schedule 4, paragraph 50 and by the Crime and County Courts Act 2013 (c. 22), Schedule 9, paragraph 52. Section 115 has been amended by the 2012 Act, Schedule 4, paragraph 54. Section 121 has been amended by the 2012 Act, Schedule 4, paragraph 59. Section 126 has been amended by the 2012 Act, Schedule 4, paragraph 63, and by the Children and Social Work Act 2017 (c. 16), Schedule 5, paragraphs 30 and 47(j). Section 128A was inserted by the Health Act 2009 (c. 21) ("the 2009 Act"), section 25, and has been amended by the 2012 Act, section 206(1). Section 129(6) has been amended by: the 2009 Act, sections 26 and 27, and Schedule 6, paragraph 38; the 2012 Act, section 207(1) and (8), and Schedule 4, paragraph 66; the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraph 121; and S.I. 2010/231. Section 176 has been amended by the 2012 Act, Schedule 4, paragraph 95. Section 180 has been amended by the 2009 Act, Schedule 6, and by the 2012 Act, section 205, and Schedule 4, paragraph 96. See section 275(1) for the definitions of "prescribed" and "regulations" that are relevant to the powers being exercised. The powers conferred by these sections are exercisable by the Secretary of State only in relation to England, by virtue of section 271(1).

"Declarations, signatures and evidence of entitlement or of payment during a pandemic etc.

- **10A.**—(1) Where, by virtue of these Regulations, a person is required to make, provide, complete or sign any declaration, or provide any evidence (including by way of completing a form or providing a certificate), but as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (a) pandemic; and
 - (b) a serious risk or potentially a serious risk to human health,

the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, for the period specified in the announcement, that requirement is to be waived or modified in the manner specified in the announcement, that requirement is waived or is as modified in the specified manner for the specified period.

- (2) Modifications under paragraph (1) may include modifications imposing requirements on a person other than the person who, but for the announcement, would be required to make, provide, complete or sign any declaration, or provide any evidence.
 - (3) An announcement under paragraph (1) may be withdrawn or amended at any time.".

Amendment of the National Health Service (Optical Charges and Payments) Regulations 2013

- **3.**—(1) The National Health Service (Optical Charges and Payments) Regulations 2013(a) are amended as follows.
 - (2) After regulation 26 (signatures and claims for payments) insert—

"Claims, signatures and evidence of eligibility during a pandemic etc.

- **26A.**—(1) Where, by virtue of these Regulations, a person is required to make a claim, complete or sign any or any part of a voucher, sign any declaration or produce any evidence, but as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (a) pandemic; and
 - (b) a serious risk or potentially a serious risk to human health,

the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, for the period specified in the announcement, that requirement is to be waived or modified in the manner specified in the announcement, that requirement is waived or is as modified in the specified manner for the specified period.

- (2) Modifications under paragraph (1) may include modifications imposing requirements on a person other than the person who, but for the announcement, would be required to make a claim, complete or sign any or any part of a voucher, sign any declaration or produce any evidence.
 - (3) An announcement under paragraph (1) may be withdrawn or amended at any time.".

Amendment of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

4.—(1) The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**b**) are amended as follows.

⁽a) S.I. 2013/461.

⁽b) S.I. 2013/349.

- (2) In regulation 6(a) (subsequent assessments)—
 - (a) before paragraph (1) insert—
 - "(A1) Any HWB that has not published a pharmaceutical needs assessment before 1st July 2020 must publish its first pharmaceutical needs assessment by 1st April 2022.
 - (A2) Any HWB that has published a pharmaceutical needs assessment before 1st July 2020 must publish a revised assessment by 1st April 2022 (but it is not required to publish a revised assessment before that date).";
 - (b) in paragraph (1), for "pharmaceutical needs assessment," substitute "or a revised assessment required by 1st April 2022 by virtue of paragraph (A2),"; and
 - (c) in paragraph (2), before "A HWB must make" insert "After it has published its first or a revised assessment required by 1st April 2022 by virtue of paragraph (A1) or (A2),",

and in its heading, after "assessments" insert "and later first assessments".

- (3) In Schedule 2 (applications in respect of pharmaceutical lists and the procedures to be followed), in paragraph 34 (taking effect of listing decisions: general)—
 - (a) in sub-paragraph (4)(b), for "6 months" substitute "12 months"; and
 - (b) after sub-paragraph (5) insert—
 - "(6) In any case where a longer period allowed by virtue of sub-paragraph (4)(c)—
 - (a) began in the 3 months prior to the coming into force of the Coronavirus Regulations, that longer period is extended so that it ends on the day that is 6 months after the day on which the Coronavirus Regulations came into force; and
 - (b) ended in the 6 months prior to the coming into force of the Coronavirus Regulations, that longer period is treated as having not ended and is extended so that it ends on the day that is 6 months after the day on which the Coronavirus Regulations came into force.
 - (7) In this paragraph, "the Coronavirus Regulations" means the National Health Service (Coronavirus) (Charges and Further Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020.".

Amendment of the Primary Ophthalmic Services Regulations 2008

- **5.**—(1) The Primary Ophthalmic Services Regulations 2008(**b**) are amended as follows.
- (2) After regulation 6 (applications and signatures by children and persons incapable) insert—

"Applications and signatures during a pandemic etc.

- **6A.**—(1) Where, by virtue of these Regulations, a person is required to complete or sign any or any part of a form, sign any declaration or provide any evidence, but as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (a) pandemic; and
 - (b) a serious risk or potentially a serious risk to human health,

the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, for the period specified in the announcement, that requirement is to be waived or modified in the manner specified in the announcement, that requirement is waived or is as modified in the specified manner for the specified period.

(2) Modifications under paragraph (1) may include modifications imposing requirements on a person other than the person who, but for the announcement, would be required to complete or sign any or any part of a form, sign any declaration or provide any evidence.

⁽a) There are no relevant amendments to regulation 6.

⁽b) S.I. 2008/1186.

(3) An announcement under paragraph (1) may be withdrawn or amended at any time.".

Amendment of the General Ophthalmic Services Contracts Regulations 2008

- **6.**—(1) The General Ophthalmic Services Contracts Regulations 2008(a) are amended as follows.
 - (2) In regulation 13(b) (testing of sight), after paragraph (6) insert—
 - "(7) Where, by virtue of this regulation, a person is required to complete or sign any or any part of a sight test form or prescription form, but as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (a) pandemic; and
 - (b) a serious risk or potentially a serious risk to human health,

the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, for the period specified in the announcement, that requirement is to be waived or modified in the manner specified in the announcement, that requirement is waived or is as modified in the specified manner for the specified period.

- (8) Modifications under paragraph (7) may include modifications imposing requirements on a person other than the person who, but for the announcement, would be required to complete or sign any or any part of a form.
 - (9) An announcement under paragraph (7) may be withdrawn or amended at any time.".

Amendment of the National Health Service (Dental Charges) Regulations 2005

- 7.—(1) The National Health Service (Dental Charges) Regulations 2005(c) are amended as follows.
 - (2) After regulation 8 (making and recovery of charges) insert—

"Applications and signatures during a pandemic etc.

- **8A.**—(1) Where, under these Regulations, a person is required to complete any or any part of a form, make any declaration or provide any evidence, but as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (a) pandemic; and
 - (b) a serious risk or potentially a serious risk to human health,

the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, for the period specified in the announcement, that requirement is to be waived or modified in the manner specified in the announcement, that requirement is waived or is as modified in the specified manner for the specified period.

- (2) Modifications under paragraph (1) may include modifications imposing requirements on a person other than the person who, but for the announcement, would be required to complete any or any part of a form, sign any declaration or provide any evidence.
 - (3) An announcement under paragraph (1) may be withdrawn or amended at any time.".

⁽a) S.I. 2008/1185.

⁽b) There are no relevant amendments to regulation 13.

⁽c) S.I. 2005/3477.

Amendment of the National Health Service (Personal Dental Services Agreements) Regulations 2005

- **8.**—(1) The National Health Service (Personal Dental Services Agreements) Regulations 2005(**a**) are amended as follows.
- (2) In Schedule 3 (other contractual terms), in paragraph 8(b) (treatment plans), after sub-paragraph (7) insert—
 - "(8) Where, by virtue of this paragraph, a person is required to include anything in a treatment plan or a summary, or to ensure a patient signs a treatment plan, but as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (a) pandemic; and
 - (b) a serious risk or potentially a serious risk to human health,

the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, for the period specified in the announcement, that requirement is to be waived or modified in the manner specified in the announcement, that requirement is waived or is as modified in the specified manner for the specified period.

- (9) Modifications under sub-paragraph (8) may include modifications imposing requirements on a person other than the person who, but for the announcement, would be required to include anything in a treatment plan or a summary or to ensure a patient signs a treatment plan.
- (10) An announcement under sub-paragraph (8) may be withdrawn or amended at any time.".

Amendment of the National Health Service (General Dental Services Contracts) Regulations 2005

- **9.**—(1) The National Health Service (General Dental Services Contracts) Regulations 2005(c) are amended as follows.
- (2) In Schedule 3 (other contractual terms), in paragraph 7(**d**) (treatment plans), after sub-paragraph (7) insert—
 - "(8) Where, by virtue of this paragraph, a person is required to include anything in a treatment plan or a summary, or to ensure a patient signs a treatment plan, but as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (a) pandemic; and
 - (b) a serious risk or potentially a serious risk to human health,

the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, for the period specified in the announcement, that requirement is to be waived or modified in the manner specified in the announcement, that requirement is waived or is as modified in the specified manner for the specified period.

- (9) Modifications under sub-paragraph (8) may include modifications imposing requirements on a person other than the person who, but for the announcement, would be required to include anything in a treatment plan or a summary or to ensure a patient signs a treatment plan.
- (10) An announcement under sub-paragraph (8) may be withdrawn or amended at any time.".

⁽a) S.I. 2015/3373

⁽b) Paragraph 8 has been amended by S.I. 2013/364.

⁽c) S.I. 2005/3361.

⁽d) Paragraph 7 has been amended by S.I. 2013/364.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Charges for Drugs and Appliances) Regulations 2015, which include the charges that are payable for the supply of NHS drugs and appliances in England. Those Regulations are amended so that the Secretary of State may, in a pandemic situation, waive or modify requirements in respect of forms and providing evidence. There is, for example, a requirement on a person paying a charge to sign a declaration that they have done so, and a requirement on a person claiming certain exemptions from paying a charge to complete a declaration of entitlement to the exemption (regulation 2(2)).

These Regulations also amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which govern the arrangements in England under Part 7 of the National Health Service Act 2006 ("the 2006 Act") for the provision of pharmaceutical services and local pharmaceutical services. The Health and Wellbeing Board of each local authority is required to produce a plan known as a pharmaceutical needs assessment. The timetable for the next assessment has been put back so that it has to be completed by 1st April 2022 rather than 1st April 2021, and 1st April 2022 is also the date for the first assessment of a new unitary authority (regulation 4(2)). Changes have also been made to extend the time periods within which successful applicants in respect of new premises need to open, and to revive recently ended time periods to give those potential NHS chemists an additional six months after the date on which these Regulations come into force within which to open (regulation 4(3)).

The General Ophthalmic Services Contracts Regulations 2008, the Primary Ophthalmic Services Regulations 2008 and the National Health Service (Optical Charges and Payments) Regulations 2013 ("the Ophthalmic Services Regulations") together set the framework for the provision of primary ophthalmic services in England, and in particular for the provision of and payments for free sight tests and the provision of vouchers to pay for or contribute towards the cost of optical appliances. These Regulations amend the Ophthalmic Services Regulations to allow the Secretary of State, in a pandemic situation, to waive or modify requirements in respect of forms and providing evidence that are part of establishing entitlement to, and providing reimbursement for, these services. There is, for example, a requirement upon an eligible person wishing to have their sight tested to sign a declaration that they are an eligible person, and a requirement for a similar declaration to be signed by an eligible person on a voucher for an optical appliance (regulations 3, 5 and 6).

The National Health Service (Dental Charges) Regulations 2005 provide for the charges payable in England in respect of the provision of primary dental services by dental practices. These Regulations amend those Regulations to allow the Secretary of State, in a pandemic situation, to waive or modify requirements in respect of forms and providing evidence that support charging for these services. There is, for example, a requirement upon a person exempt from payment of dental charges to make a written declaration to that effect, and a requirement upon a person who is not exempt to provide a written acknowledgement to that effect (regulation 7).

These Regulations also amend the National Health Service (Personal Dental Services Agreements) Regulations 2005 and the National Health Service (General Dental Services Contracts) Regulations 2005, which make provision in respect of the services provided in England under a personal dental services agreement and a general dental services contract made pursuant to Part 5 of the 2006 Act. These Regulations amend those Regulations to allow the Secretary of State, in a pandemic situation, to waive or modify requirements in respect of the treatment plans and summaries provided by service providers (regulations 8 and 9).

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