

2021 No. 169

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Charges and Pharmaceutical and
Local Pharmaceutical Services) (Coronavirus) (Amendment)
Regulations 2021**

Made - - - - at 2.02 p.m. on 19th February 2021

Laid before Parliament at 2.55 p.m. on 19th February 2021

Coming into force - - - - 1st March 2021

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 126(2), 129(6), 132, 172(1), 178, 182, 184(1) and 272(7) and (8) of, and paragraph 3(1) and (3)(c) and (d) of Schedule 12 to, the National Health Service Act 2006(a).

Citation, commencement, application and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Amendment) Regulations 2021.

(2) These Regulations come into force on 1st March 2021.

(3) These Regulations extend to England and Wales and apply in relation to England only(b).

(4) In these Regulations, “the PLPS Regulations” means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(c).

Amendment of regulation 2 of the PLPS Regulations

2. In regulation 2(1) of the PLPS Regulations(d) (interpretation), at the appropriate place insert—

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- (a) 2006 c.41. Section 126 has been amended by the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”), sections 213(7)(k) and 220(7), and Schedule 4, paragraph 63, and the Children and Social Work Act 2017 (c. 16), Schedule 5, paragraph 30. Section 129(6) has been amended by: the Health Act 2009 (c. 21) (“the 2009 Act”), sections 26 and 27, and Schedule 6; the 2012 Act, section 207(1) to (9), and Schedule 4, paragraph 66; the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraph 121; and S.I. 2010/231. Section 132 has been amended by the 2012 Act, Schedule 4, paragraph 69, by the Protection of Freedoms Act 2012, Schedule 9, paragraph 122, and by S.I. 2007/289 and 2010/22 and 231. Paragraph 3 of Schedule 12 has been amended by: the 2009 Act, section 29(13) to (15); the 2012 Act, Schedule 4, paragraph 93(4); and the Crime and Courts Act 2013 (c. 22), Schedule 9, paragraph 52(1)(b) and (2). See section 275(1) of the National Health Service Act 2006 (“the 2006 Act”) for the meanings given to “prescribed” and “regulations”.
- (b) See section 271(1) of the National Health Service Act 2006, by virtue of which the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England.
- (c) S.I. 2013/349, as amended.
- (d) Regulation 2 has been amended by S.I. 2015/137, 570, 1862 and 1879, 2016/696 and 1077, 2018/1114, 2019/593, 990 and 1094, and 2020/351 and 1126.

““prescription item” means an item available on prescription, whether or not it is supplied in pursuance of a prescription or another basis for supply (for example a serious shortage protocol or a patient group direction);” and

““PTPGD” means a pandemic treatment patient group direction, which is a patient group direction—

- (a) relating to the supply of a prescription only medicine to be used for the prevention of or as a treatment for a disease that is, or in anticipation of it being imminently, pandemic; and
- (b) which is in accordance with regulation 233 of the Human Medicines Regulations 2012(a) (exemption for supply etc under a PGD by a person conducting a retail pharmacy business);”.

Amendment of Schedule 4 to the PLPS Regulations

3.—(1) Part 2 of Schedule 4 to the PLPS Regulations (terms of service of NHS pharmacists – essential services) is amended as follows.

(2) In paragraph 5B(b) (supply in accordance with a PTP)—

- (a) in sub-paragraph (1)(a), after “a PTP” insert “or a PTPGD”;
- (b) after sub-paragraph (1) insert—

“(1A) Where P considers—

- (a) on the basis of a request for the supply of a drug in accordance with a PTP or a PTPGD that has been approved by the NHSCB as a basis for supply as part of pharmaceutical services;
- (b) having made the appropriate checks; and
- (c) having regard to what is reasonable and appropriate,

that a person is entitled to be supplied with the drug in accordance with the PTP or PTPGD as part of pharmaceutical services, P must, with reasonable promptness, provide the drug requested.”; and

(c) in sub-paragraph (2), after “sub-paragraph (1)(b)” insert “or (1A)”, and in the heading of that paragraph, after “a PTP” insert “or a PTPGD”.

(3) In paragraph 8(c) (providing ordered drugs or appliances)—

- (a) in sub-paragraph (17), after “a PTP” insert “or a PTPGD”; and
- (b) in sub-paragraph (18)—
 - (i) after “a PTP” insert “or a PTPGD”, and
 - (ii) after “particular PTP” insert “or PTPGD”.

(4) In paragraph 9(d) (refusal to provide drugs or appliances ordered)—

- (a) in sub-paragraph (5)—
 - (i) for “provide an order” substitute “fulfil an order or a request”,
 - (ii) after “a PTP” insert “or a PTPGD”, and
 - (iii) in paragraph (a), after “genuine order” insert “or valid request”; and
- (b) in sub-paragraph (6)—
 - (i) after “a PTP” insert “or a PTPGD”,
 - (ii) after “an order” insert “or a request”,

(a) S.I. 2012/1916; regulation 233 has been amended by S.I. 2013/235, 2015/1053 and 2020/1594.

(b) Inserted by S.I. 2020/1126.

(c) Amended by S.I. 2019/990 and 2020/1126.

(d) Amended by S.I. 2018/1114, 2019/990 and 2020/1126.

(iii) after “with the PTP”, at both places, insert “or PTPGD”.

(5) After paragraph 22A(a) (home delivery service while a disease is or in anticipation of a disease being imminently pandemic etc.) insert—

“Home delivery of notified items while a disease is or in anticipation of a disease being imminently pandemic etc.

22AA.—(1) Before dispensing a notified item on a prescription form or supplying it in accordance with a serious shortage protocol, a PTP or a PTPGD, an NHS pharmacist (P) must provide a home delivery option to eligible patients in respect of that item.

(2) For the purposes of this paragraph, a “notified item” is an item that, 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,

is the subject of an announcement made by the NHSCB, with the agreement of the Secretary of State, to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, eligible patients are entitled to be provided with a home delivery option in respect of that item, if it is supplied to them as part of pharmaceutical services.

(3) Where P is to, or may be required to, dispense a notified item on a prescription form or supply it in accordance with a serious shortage protocol, a PTP or a PTPGD, P must ascertain from—

- (a) an eligible patient—
 - (i) who has contacted P about the home delivery of a notified item, or
 - (ii) who is a person whom P considered, on the basis of an order or request for a notifiable item, might be an eligible person and accordingly, in the ordinary exercise of professional skill and judgement, made the appropriate checks and determined that they were; or
- (b) a person who may make an application for pharmaceutical services on behalf of that eligible patient (a “duly authorised person”) who has contacted P about the home delivery of a notified item,

whether or not the item could be supplied via a duly authorised person, and if it could, then supplying the item via a duly authorised person is the home delivery option which P must provide.

(4) Where paragraph (3) does not apply, the home delivery option that P must provide must comprise—

- (a) P delivering the item to the eligible patient’s home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);
- (b) P arranging for an item dispensed by P to be delivered by another NHS pharmacist or by an LPS contractor to the eligible patient’s home or to an alternative address agreed with the patient or a duly authorised person; or
- (c) if P is unable to deliver the item or arrange for its delivery by another NHS pharmacist or by an LPS contractor, P arranging for the dispensing or supply of the item by another NHS pharmacist or by an LPS contractor who would be able to deliver the item to the eligible patient’s home or to an alternative address agreed with the patient or a duly authorised person.

(a) Inserted by S.I. 2020/351.

(5) Paragraph (1) does not apply where the eligible patient or a duly authorised person is already at P's pharmacy premises for the purposes of being supplied with the notifiable item.

(6) Notwithstanding the foregoing provisions of this Part, in any case of a supply in accordance with a home delivery option, if but for this sub-paragraph that supply would need to be made with reasonable promptness, P may instead, in the exercise of professional skill and judgment, make the supply within a reasonable timescale.

(7) Where arrangements are in place which enable an NHS pharmacist to make a delivery as mentioned in sub-paragraph (4)(a) or (b) as part of a directed service, the NHS pharmacist must deliver the item as part of that directed service.

(8) This paragraph does not apply to an NHS pharmacist in respect of distance selling premises.”.

Amendment of Schedule 6 to the PLPS Regulations

4.—(1) Schedule 6 to the PLPS Regulations (terms of service of dispensing doctors) is amended as follows.

(2) In paragraph 3B(a) (supply in accordance with a PTP)—

(a) in sub-paragraph (1)(a), after “a PTP” insert “or a PTPGD”;

(b) after sub-paragraph (1) insert—

“(1A) Where D considers—

(a) on the basis of a request for the supply of a drug in accordance with a PTP or a PTPGD that has been approved by the NHSCB as a basis for supply as part of pharmaceutical services;

(b) having made the appropriate checks; and

(c) having regard to what is reasonable and appropriate,

that a person is entitled to be supplied with the drug in accordance with the PTP or PTPGD as part of pharmaceutical services, D must, with reasonable promptness, provide the drug requested.”; and

(c) in sub-paragraph (3)—

(i) after “sub-paragraph (1)” insert “or (1A)”,

(ii) after “a PTP” insert “or a PTPGD”, and

(iii) after “particular PTP” insert “or PTPGD”,

and in the heading of that paragraph, after “a PTP” insert “or a PTPGD”.

(3) In paragraph 6(b) (refusal to provide drugs or appliances ordered)—

(a) in sub-paragraph (5)—

(i) for “provide an order” substitute “fulfil an order or a request”,

(ii) after “a PTP” insert “or a PTPGD”, and

(iii) in paragraph (a), after “genuine order” insert “or valid request”; and

(b) in sub-paragraph (6)—

(i) after “a PTP” insert “or a PTPGD”,

(ii) after “an order” insert “or a request”,

(iii) after “with the PTP”, at both places, insert “or PTPGD”.

(a) Inserted by S.I. 2020/1126.

(b) Amended by S.I. 2018/1114, 2019/990 and 2020/1126.

(4) After paragraph 7A(a) (home delivery service while a disease is or in anticipation of a disease being imminently pandemic etc.) insert—

“Home delivery of notified items while a disease is or in anticipation of a disease being imminently pandemic etc.

7AA.—(1) Before dispensing a notified item on a prescription form or supplying it in accordance with a serious shortage protocol, a PTP or a PTPGD, a dispensing doctor (D) must provide a home delivery option to eligible patients in respect of that item.

(2) For the purposes of this paragraph, a “notified item” is an item that, 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,

is the subject of an announcement made by the NHSCB, with the agreement of the Secretary of State, to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, eligible patients are entitled to be provided with a home delivery option in respect of that item, if it is supplied to them as part of pharmaceutical services.

(3) Where D is to, or may be required to, dispense a notified item on a prescription form or supply it in accordance with a serious shortage protocol, a PTP or a PTPGD, D must ascertain from—

- (a) an eligible patient—
 - (i) who has contacted D about the home delivery of a notified item, or
 - (ii) who is a person whom D considered, on the basis of an order or request for a notifiable item, might be an eligible person and accordingly, in the ordinary exercise of professional skill and judgement, made the appropriate checks and determined that they were; or
- (b) a person who may make an application for pharmaceutical services on behalf of that eligible patient (a “duly authorised person”) who has contacted D about the home delivery of a notified item,

whether or not the item could be supplied via a duly authorised person, and if it could, then supplying the item via a duly authorised person is the home delivery option which D must provide.

(4) Where paragraph (3) does not apply, the home delivery option that D must provide must comprise—

- (a) D delivering the item to the eligible patient’s home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);
- (b) D arranging for an item dispensed by D to be delivered by another dispensing doctor, or by an NHS pharmacist or an LPS contractor, to the eligible patient’s home or to an alternative address agreed with the patient or a duly authorised person; or
- (c) if D is unable to deliver the item or arrange for its delivery by another dispensing doctor, or by an NHS pharmacist or an LPS contractor, D arranging for the dispensing or supply of the item by another dispensing doctor, or by an NHS pharmacist or an LPS contractor, who would be able to deliver the item to the eligible patient’s home or to an alternative address agreed with the patient or a duly authorised person.

(a) Inserted by S.I. 2020/351.

(5) Paragraph (1) does not apply where the eligible patient or a duly authorised person is already at D's listed dispensing premises for the purposes of being supplied with the notifiable item.

(6) Notwithstanding the foregoing provisions of this Schedule, in any case of a supply in accordance with a home delivery option, if but for this sub-paragraph that supply would need to be made with reasonable promptness, D may instead, in the exercise of professional skill and judgment, make the supply within a reasonable timescale.”.

Amendment of Schedule 7 to the PLPS Regulations

5.—(1) In Schedule 7 to the PLPS Regulations (mandatory terms for LPS schemes) is amended as follows.

(2) In paragraph 10A(a) (home delivery service while a disease is or in anticipation of a disease being imminently pandemic etc.), in sub-paragraph (4), for “listed dispensing” substitute “chemist”.

(3) After paragraph 10A, insert—

“Home delivery of notified items while a disease is or in anticipation of a disease being imminently pandemic etc.

10AA.—(1) Before dispensing a notified item on a prescription form or supplying it in accordance with a serious shortage protocol, an LPS contractor (C) must provide a home delivery option to eligible patients in respect of that item.

(2) For the purposes of this paragraph, a “notified item” is an item that, 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,

is the subject of an announcement made by the NHSCB, with the agreement of the Secretary of State, to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, eligible patients are entitled to be provided with a home delivery option in respect of that item, if it is supplied to them as part of local pharmaceutical services.

(3) Where C is to, or may be required to, dispense a notified item on a prescription form or supply it in accordance with a serious shortage protocol, C must ascertain from—

- (a) an eligible patient—
 - (i) who has contacted C about the home delivery of a notified item, or
 - (ii) who is a person whom C considered, on the basis of an order or request for a notifiable item, might be an eligible person and accordingly, in the ordinary exercise of professional skill and judgement, made the appropriate checks and determined that they were; or
- (b) a person who may make an application for pharmaceutical services on behalf of that eligible patient (a “duly authorised person”) who has contacted C about the home delivery of a notified item,

whether or not the item could be supplied via a duly authorised person, and if it could, then supplying the item via a duly authorised person is the home delivery option which C must provide.

(4) Where paragraph (3) does not apply, the home delivery option that C must provide must comprise—

(a) Inserted by S.I. 2020/351.

- (a) C delivering the item to the eligible patient’s home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);
- (b) C arranging for an item dispensed by C to be delivered by another LPS contractor or by an NHS pharmacist to the eligible patient’s home or to an alternative address agreed with the patient or a duly authorised person; or
- (c) if C is unable to deliver the item or arrange for its delivery by another LPS contractor or by an NHS pharmacist, C arranging for the dispensing or supply of the item by another LPS contractor or by an NHS pharmacist who would be able to deliver the item to the eligible patient’s home or to an alternative address agreed with the patient or a duly authorised person.

(5) Paragraph (1) does not apply where the eligible patient or a duly authorised person is already at C’s chemist premises for the purposes of being supplied with the notifiable item.

(6) Notwithstanding the foregoing provisions of this Schedule, in any case of a supply in accordance with a home delivery option, if but for this sub-paragraph that supply would need to be made with reasonable promptness, C may instead, in the exercise of professional skill and judgment, make the supply within a reasonable timescale.”.

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

6.—(1) The National Health Service (Charges for Drugs and Appliances) Regulations 2015(a) are amended as follows.

- (2) In regulation 2(b) (interpretation), in paragraph (1), at the appropriate place insert—
 - ““prescription item” means an item available on prescription, whether or not it is supplied in pursuance of a prescription or another basis for supply (for example a serious shortage protocol or a patient group direction);”.
- (3) In regulation 13 (exemption from charges: risks to public health)—
 - (a) in paragraph (1), for “drugs”, at each place where it occurs, substitute “prescription items”;
 - (b) in paragraph (1)(b), for “protocols” substitute “a prescription form, a patient group direction, a serious shortage protocol or a protocol”; and
 - (c) in paragraph (2), for “drug”, at each place where it occurs, substitute “prescription item”.

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

Nadhim Zahawi
Parliamentary Under Secretary of State
Department of Health and Social Care

2.02 p.m. on 19th February 2021

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the PLPS Regulations”). The PLPS Regulations govern the arrangements in England, under Part 7 of the National Health Service Act 2006, for the provision of pharmaceutical and local pharmaceutical services. The PLPS Regulations include the NHS terms of service of four different types of provider: retail pharmacy businesses that are on pharmaceutical lists held by the NHS Commissioning Board (the businesses are known as “pharmacy contractors”, and the Board as NHS England and NHS Improvement – “NHSE-I”);

(a) S.I. 2015/750.

(b) Amended by S.I. 2015/1879, 2016/696 and 1077, 2018/1114 and 2019/248 and 1094.

dispensing appliance contractors; dispensing doctors; and retail pharmacy businesses that hold local pharmaceutical services contracts (known as “LPS contractors”). These Regulations also amend the National Health Service (Charges for Drugs and Appliances) Regulations 2015 (“the Charges Regulations”), which include the charges payable for the supply of drugs and appliances as part of the NHS in England.

These Regulations contain measures that are part of the response to the coronavirus pandemic.

The Charges Regulations are amended to ensure that supplies of prescription items for or in anticipation of pandemic disease, or in other serious emergencies, either on prescription or pursuant to a patient group direction or serious shortage protocol, are free of charge – if they relate to that disease (in a pandemic situation) and arrangements have been made to that effect by the Secretary of State, or by another NHS body with the approval of the Secretary of State. Previously, this only applied to such supplies if they were supplies of drugs and, in a pandemic situation, if the supplies were in accordance with pandemic treatment protocols (“PTPs”) under regulation 247 of the Human Medicines Regulations 2012 (regulation 6).

Provision is also made so that pharmacy contractors and dispensing doctors are required to supply against a patient group direction that is approved by NHSE-I and relates to the supply of a prescription only medicine to be used for the prevention of, or as a treatment for, a disease that is, or in anticipation of it being imminently, pandemic (known as a pandemic treatment patient group direction – “PTPGD”) in the same circumstances in which they are required to supply such medicines against PTPs. Provision is made so that PTPGD or PTP supply may be triggered not only by an electronic message of a type approved by NHSE-I (the situation prior to these Regulations) but also following individual assessment of the patient’s entitlement. There are consequential amendments relating to these requirements that deal with matters such as dispensing labels (regulations 2, 3(2) to (4) and 4(2) and (3)).

Pharmacy contractors, dispensing doctors and LPS contractors may already be required by NHSE-I, in a pandemic situation, to provide a home delivery option to patients who are required to stay at home in order to assist in the management of the pandemic. These pre-existing arrangements apply to all the prescriptions that the patient receives. These Regulations allow the NHE-I additionally to require pharmacy contractors, dispensing doctors and LPS contractors to provide a home delivery option in respect of specific prescription items to eligible patients (for example, but not limited to, treatments for a disease that is pandemic). In the case of dispensing doctors and pharmacy contractors, this home delivery option is further extended to specific items supplied under a PTP or PTPGD as part of pharmaceutical services (regulations 3(5), 4(4) and 5(3)). An error in one of the existing home delivery option provisions has also been corrected (regulation 5(2)).

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