
STATUTORY INSTRUMENTS

2021 No. 1346

The National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021

PART 2

Amendments to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

Amendment of regulation 2 of the PLPS Regulations

- 2.—**(1) Regulation 2 of the PLPS Regulations⁽¹⁾ (interpretation) is amended as follows.
- (2) At the appropriate places in the alphabetical order insert—
- ““listed prescription items voucher” means a form which—
- (a) is provided or approved by the NHSCB for the purposes of ordering a prescription item mentioned in regulation 13(1) of the Charges Regulations (exemption from charges: risks to public health); and
- (b) may be an electronic form sent or to be sent via a secure service approved for this purpose by the NHSCB;”;
- ““LPIV” means a listed prescription items voucher;”.

Amendment of regulation 6 of the PLPS Regulations

- 3.—**(1) Regulation 6 of the PLPS Regulations⁽²⁾ (subsequent assessments and later first assessments) is amended as follows.
- (2) In paragraph (A1)—
- (a) before “Any HWB” insert “Subject to paragraph (A3),”; and
- (b) for “1st April” substitute “1st October”.
- (3) In paragraph (A2), for “1st April” substitute “1st October”.
- (4) After paragraph (A2) insert—
- “(A3) Any HWB established on or after 1st January 2022 must publish its first pharmaceutical needs assessment no later than twelve months after it is established.”.

(1) Amended by [S.I. 2015/137](#), [570](#), [1862](#) and [1879](#), [2016/696](#) and [1077](#), [2018/1114](#), [2019/593](#), [990](#) and [1094](#), [2020/351](#) and [1126](#), and [2021/169](#).

(2) Amended by [S.I. 2016/1077](#) and [2020/885](#).

(5) In paragraph (1), for from “After it” to “paragraph (A2),” substitute “Subject to paragraph (2), after it has published its first assessment as required by paragraph (A1) or (A3), or a revised assessment as required by paragraph (A2) or (2).”.

(6) In paragraph (2), for from “After it” to “a HWB” substitute “Each HWB that has published a pharmaceutical needs assessment”.

(7) After paragraph (3), insert—

“(3A) Pending the publication of a first pharmaceutical needs assessment under paragraph (A1) or (A3), a HWB (“HWB1”) may publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of a pharmaceutical needs assessment by another HWB (“HWB2”) prior to the establishment of HWB1, where—

- (a) the changes are relevant to the granting of applications referred to in section 129(2)(c)(i) or (ii) of the 2006 Act in respect of premises in a locality in the area of HWB1 that was, prior to HWB1’s establishment, in the area of HWB2; and
- (b) HWB1 is in the course of making its first pharmaceutical needs assessment and is satisfied that immediate modification of HWB2’s assessment is essential in order to prevent significant detriment to the provision of pharmaceutical services in that locality in the area of HWB1.”.

Amendment of regulation 7 of the PLPS Regulations

4.—(1) Regulation 7 of the PLPS Regulations (temporary extension of pharmaceutical needs assessments and access by the NHSCB and HWBs to pharmaceutical needs assessments) is amended as follows.

(2) In its heading, for “Primary Care Trust” substitute “earlier”.

(3) Omit paragraph (1).

(4) Before paragraph (2), insert—

“(1A) Prior to the publication by a HWB (“HWB1”) of the first pharmaceutical needs assessment that it prepares for its area, as required by regulation 6(A1) or (A3), the pharmaceutical needs assessment that relates to any locality within its area is the pharmaceutical needs assessment of the HWB (“HWB2”) for that locality prior to the establishment of HWB1, read with—

- (a) any supplementary statement relating to that assessment published by HWB2 under regulation 6(3) (which has become part of that assessment); and
- (b) any supplementary statement relating to that assessment published by HWB1 under regulation 6(3A).”.

(5) In paragraph (2)(b), for “6(3), in relation to a Primary Care Trust’s” substitute “6(3A), in relation to another HWB’s”.

New regulation 21A of the PLPS Regulations

5. After regulation 21 of the PLPS Regulations (future improvements or better access: consequences of additional matters), insert—

“PNA based applications for new premises offering additional or different opening hours

21A.—(1) Paragraph (2) applies where the NHSCB receives a routine application which is in respect of premises not already listed, where—

- (a) the applicant’s stated intention (in accordance with paragraph 7(1)(a) of Schedule 2) is to meet a need, or secure improvements or better access, identified in the relevant pharmaceutical needs assessment (whether current or future gaps in provision); and
- (b) the need is, or the improvements are or the better access is, in respect of the days on which or the times at which essential services are provided in the area of the relevant HWB.

(2) In determining whether or not it is satisfied as mentioned in section 129(2A) of the 2006 Act⁽³⁾ (regulations as to pharmaceutical services), the NHSCB must have regard to whether granting the application would result in an undesirable increase in the availability of essential services in the area of the relevant HWB.

(3) If the NHSCB is satisfied that granting the application would result in the undesirable increase in availability mentioned in paragraph (2), it must refuse the application.”

Amendment of regulation 91 of the PLPS Regulations

6.—(1) Regulation 91 of the PLPS Regulations (remuneration of NHS chemists: instruments of appointment of the NHSCB) is amended as follows.

(2) For paragraph (5) substitute—

“(5) Before determining any remuneration payable in respect of an enhanced service, the NHSCB must consult—

- (a) if the service is to be provided on the basis of a service specification that sets standard conditions nationally (including with regard to remuneration), the body that is, for the time being, the body consulted under section 165(1)(a) of the 2006 Act in respect of pharmaceutical remuneration of NHS pharmacists; or
- (b) otherwise, any Local Pharmaceutical Committee for the area in which the service is to be provided.”

Amendment of Part 2 of Schedule 4 to the PLPS Regulations

7.—(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⁽⁴⁾ (supply in accordance with a PTP or a PTPGD), after sub-paragraph (2) insert—

“(3) Sub-paragraph (1) does not apply where arrangements are in place for the provision of the drug (whether by P or otherwise) ordered pursuant to the PTP or PTPGD as part of a directed service which includes arrangements for the provision of such a drug ordered in accordance with such a PTP or PTPGD.

(4) Sub-paragraph (1A) does not apply where arrangements are in place for the provision of the drug (whether by P or otherwise) requested in accordance with the PTP or PTPGD as part of a directed service which includes arrangements for the provision of such a drug requested in accordance with such a PTP or PTPGD.”

(3) Subsection (2A) was inserted by the Health Act 2009 (c. 21), section 26(3), and amended by the Health and Social Care Act 2012 (c. 7), section 207(4), and Schedule 4, paragraph 66(5).

(4) Inserted by S.I. 2020/1126 and amended by S.I. 2021/169.

(3) After paragraph 5B insert—

“Supply in accordance with a LPIV

5C.—(1) Subject to the following provisions of this Part, where—

- (a) an NHS Pharmacist (P) receives a LPIV; and
- (b) a person who is entitled to be supplied by P with a prescription item ordered on the LPIV requests the provision of the item in accordance with that LPIV,

P must, with reasonable promptness, provide the prescription item so ordered.

(2) If a person who is entitled as mentioned in sub-paragraph (1)(b) asks P to do so—

- (a) P must give an estimate of the time when the prescription item will be ready; and
- (b) if they are not ready by then, P must give a revised estimate of the time when the item will be ready (until it is ready).

(3) Sub-paragraph (1) does not apply where arrangements are in place for the provision of the item (whether by P or otherwise) ordered on the LPIV as part of a directed service which includes arrangements for the provision of such an item ordered on such a LPIV.”

(4) In paragraph 8(5) (providing ordered drugs or appliances)—

- (a) in sub-paragraph (15), after “paragraph 5” insert “or 5C”; and
- (b) in sub-paragraph (17), before “a PTP” insert “a LPIV,”.

(5) In paragraph 9(6) (refusal to provide drugs or appliances ordered)—

- (a) in sub-paragraph (5), before “a PTP” insert “a LPIV,”; and
- (b) in sub-paragraph (6)—
 - (i) before “a PTP” insert “a LPIV,”
 - (ii) before “the PTP”, at both places, insert “the LPIV,”.

Amendment of Part 4 of Schedule 4 to the PLPS Regulations

8.—(1) Part 4 of Schedule 4 to the PLPS Regulations (terms of service of NHS pharmacists – other terms of service) is amended as follows.

(2) In paragraph 28(7) (clinical governance and the promotion of healthy living), in sub-paragraph (2), after paragraph (c) insert—

- “(ca) at the request of the NHSCB, a pandemic response programme, which includes—
 - (i) conducting an infection control risk assessment, in the approved manner,
 - (ii) appropriate infection control measures at P’s pharmacy premises, having regard to that infection control risk assessment and to any approved particulars designed to support, in a proportionate manner, the safety of service users and pharmacy staff in particular in circumstances where services users or pharmacy staff may be, or are known or suspected to be, suffering from the pandemic disease,
 - (iii) arrangements, which may be approved arrangements, for communicating with potential service users about service availability and service provision at or from P’s pharmacy premises during the pandemic,
 - (iv) arrangements for appropriate updating of the standard operating procedures mentioned in sub-paragraph (c)(v) and any business continuity plan of P, and

(5) Amended by S.I. 2019/990, 2020/1126 and 2021/169.

(6) Amended by S.I. 2018/1114, 2019/990, 2020/1126 and 2021/169.

(7) Amended by S.I. 2015/58, 2016/1077 and 2020/1126.

- (v) arrangements for appropriate updating of the premises standards programme mentioned in sub-paragraph (g) (including in response to any new approved particulars under sub-paragraph (g)(ii) that are in response to the pandemic), but prior to making such a request (or revising the terms of such a request), the NHSCB must consult the body that is, for the time being, the body consulted under section 165(1) (a) of the 2006 Act in respect of pharmaceutical remuneration of NHS pharmacists;”.

Amendment of Schedule 6 to the PLPS Regulations

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

- (2) In paragraph 3B(8) (supply in accordance with a PTP or PTPGD)—
- (a) in sub-paragraph (1), for “this Part,” substitute “this Schedule,”;
 - (b) in sub-paragraph (1)(b), after “supplied with that drug” insert “by D (Part 8 and this Schedule having that effect)”;
 - (c) in sub-paragraph (1A), after “supplied with the drug” insert “by D (Part 8 and this Schedule having that effect)”;
 - (d) after sub-paragraph (3) insert—

“(4) Sub-paragraph (1) does not apply where arrangements are in place for the provision of the drug ordered pursuant to the PTP or PTPGD as part of a directed service which includes arrangements for the provision of such a drug ordered in accordance with such a PTP or PTPGD.

(5) Sub-paragraph (1A) does not apply where arrangements are in place for the provision of the drug requested in accordance with the PTP or PTPGD as part of a directed service which includes arrangements for the provision of such a drug requested in accordance with such a PTP or PTPGD.”.

- (3) After paragraph 3B insert—

“Supply in accordance with a LPIV

3C.—(1) Subject to the following provisions of this Schedule, where—

- (a) a dispensing doctor (D) receives a LPIV; and
- (b) a person who is entitled to be supplied by D (Part 8 and this Schedule having that effect) with a prescription item ordered on the LPIV requests the provision of the item in accordance with that LPIV,

D must, with reasonable promptness, provide the prescription item so ordered.

- (2) If a person who is entitled as mentioned in sub-paragraph (1)(b) asks D to do so—

- (a) D must give an estimate of the time when the prescription item will be ready; and
- (b) if they are not ready by then, D must give a revised estimate of the time when the item will be ready (until it is ready).

(3) Sub-paragraph (1) does not apply where arrangements are in place for the provision of the item ordered on the LPIV as part of a directed service which includes arrangements for the provision of such an item ordered on such a LPIV.”.

- (4) In paragraph 6(9) (refusal to provide drugs or appliances ordered)—

(8) Inserted by [S.I. 2020/1126](#) and amended by [S.I. 2021/169](#).

(9) Amended by [S.I. 2018/1114](#), [2019/990](#), [2020/1126](#) and [2021/169](#).

- (a) in sub-paragraph (5), before “a PTP” insert “a LPIV;” and
- (b) in sub-paragraph (6)—
 - (i) before “a PTP” insert “a LPIV;”, and
 - (ii) before “the PTP”, at each place where it occurs (twice), insert “the LPIV;”.

Amendment of Schedule 7 to the PLPS Regulations

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

- (2) After paragraph 3A(10) (supply in accordance with a SSP) insert—

“Supply in accordance with a LPIV

3B.—(1) Subject to the following provisions of this Schedule, where—

- (a) a LPS Contractor (C) receives a LPIV; and
- (b) a person who is entitled to be supplied by C with a prescription item ordered on the LPIV requests the provision of the item in accordance with that LPIV,

C must, with reasonable promptness, provide the prescription item so ordered.

- (2) If a person who is entitled as mentioned in sub-paragraph (1)(b) asks C to do so—

- (a) C must give an estimate of the time when the prescription item will be ready; and
- (b) if they are not ready by then, C must give a revised estimate of the time when the item will be ready (until it is ready).

(3) Sub-paragraph (1) does not apply where arrangements are in place for the provision of the item ordered on the LPIV as part of a directed service which includes arrangements for the provision of such an item ordered on such a LPIV.”

- (3) In paragraph 6(11) (providing ordered drugs or appliances)—

- (a) in sub-paragraph (13), after “paragraph 3” insert “or 3B”; and
- (b) after sub-paragraph (14) insert—

“(15) Sub-paragraphs (3) to (8) apply to the provision of a drug in accordance with a LPIV as they apply to the provision of a drug in accordance with a prescription form or a repeatable prescription (or an associated batch issue).”

- (4) In paragraph 7(12) (refusal to provide drugs or appliances ordered), after sub-paragraph (4) insert—

“(5) C may refuse to provide a prescription item that is or is purportedly ordered on a LPIV where—

- (a) C reasonably believes it is not a genuine order for the person who requests, or on whose behalf is requested, the provision of the prescription item;
- (b) providing it would be contrary to C’s clinical judgement;
- (c) C or other persons are subjected to or threatened with violence by the person who requests the provision of the prescription item, or by any person accompanying that person; or
- (d) the person who requests the provision of the prescription item, or any person accompanying that person, commits or threatens to commit a criminal offence.

(10) Inserted by S.I. 2019/990.

(11) Amended by S.I. 2019/990.

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

(6) C must refuse to provide a prescription item that is or is purportedly ordered on a LPIV where C is satisfied that C is not entitled to provide it or the prescriber was not entitled to prescribe it.”.