STATUTORY INSTRUMENTS

2021 No. 1346

NATIONAL HEALTH SERVICE, ENGLAND

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

Made - - - - *24th November 2021*

Laid before Parliament *30th November 2021*

Coming into force in accordance with regulation 1(2)

CONTENTS

PART 4

Amendments to the National Health Service (General Medical Services Contracts) Regulations 2015 and the National Health Service (Personal Medical Services Agreements) Regulations 2015

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 85, 89(1), (2)(a), (c) and (d), 94(1) and (3)(f), 126(2), 128A, 129(1), (2), (2A), (2C) and (6), 132, 172(1), 178, 182, 184(1) and 272(7) and (8) of, and paragraph 3(1) and (3)(c), (d) and (f) of Schedule 12 to, the National Health Service Act 2006(**a**).

PART 1

Introductory

Citation, commencement, extent, application and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021.

(2) As regards the commencement of these Regulations—

(a) this regulation and regulations 2, 6, 7 and 9 to 24 come into force on the twenty-first day after the day on which these Regulations are laid before Parliament; and

(b) regulations 3 to 5 and 8 come into force on 1st January 2022.

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

(4) In these Regulations—

(**a**) 2006 c. 41. Section 89 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), sections 28(1) and 202(2), and Schedule 4, paragraph 34. Section 94 has been amended by the 2012 Act, section 28(2), and Schedule 4, paragraph 38, and by the Crime and County Courts Act 2013 (c. 22) ("the 2013 Act"), Schedule 9, paragraph 52(1)(b) and (2). Section 126 has been amended by 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 128A was inserted by the Health Act 2009 (c. 21) ("the 2009 Act"), section 25, and 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; the 2012 Act, section 207(1) to (9), and Schedule 4, paragraph 66; the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraphs 120 and 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) and (14); the 2012 Act, Schedule 4, paragraph 93(4); and the 2013 Act, 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.

"the Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2015(**a**);

"the GMS Regulations" means the National Health Service (General Medical Services Contracts) Regulations 2015(**b**);

"the PLPS Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**c**); and

"the PMS Regulations" the National Health Service (Personal Medical Services Agreements) Regulations 2015(**d**).

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(**e**) (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;"; and

""LPIV" means a listed prescription items voucher;".

Amendment of regulation 6 of the PLPS Regulations

3.—(1) Regulation 6 of the PLPS Regulations(**f**) (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.".

(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—

(**a**) S.I. 2015/570, as amended.
(**b**) S.I. 2015/1862, as amended.
(**c**) S.I. 2013/349, as amended.
(**d**) S.I. 2015/1879, as amended.
(**e**) 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.
(**f**) Amended by S.I. 2016/1077 and 2020/885.

"(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(**a**) (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(**b**) (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) 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).

(**a**) 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).

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

(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(**a**) (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(**b**) (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(**c**) (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

(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(**d**) (supply in accordance with a PTP or PTPGD)—

(a) in sub-paragraph (1), for "this Part," substitute "this Schedule,";

(**a**) Amended by S.I. 2019/990, 2020/1126 and 2021/169.
(**b**) Amended by S.I. 2018/1114, 2019/990, 2020/1126 and 2021/169.
(**c**) Amended by S.I. 2015/58, 2016/1077 and 2020/1126.
(**d**) Inserted by S.I. 2020/1126 and amended by S.I. 2021/169.

(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(**a**) (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,", 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(**b**) (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

(**a**) Amended by S.I. 2018/1114, 2019/990, 2020/1126 and 2021/169.
(**b**) Inserted by S.I. 2019/990.

(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(**a**) (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(**b**) (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.

(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.".

PART 3

Amendments to the National Health Service (Charges for Drugs and Appliances) Regulations 2015

Amendment of regulation 2 of the Charges Regulations

11.—(1) Regulation 2 of the Charges Regulations(**c**) (interpretation) is amended as follows.

(2) In paragraph (1), at the appropriate places in the alphabetical order insert—

""exemption certificate" means a certificate conferring exemption that is to be applied for in accordance with regulation 15(1);"; and

""health care professional" means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and

(**a**) Amended by S.I. 2019/990.
(**b**) Amended by S.I. 2018/1114, 2019/990 and 2020/1126.
(**c**) Amended by S.I. 2015/1879, 2016/696 and 1077, 2018/1114, 2019/248, 990 and 1094 and 2021/169.

Health Care Professions Act 2002(**a**) (the Professional Standards Authority for Health and Social Care);".

Amendment of regulation 13 of the Charges Regulations

12.—(1) Regulation 13 of the Charges Regulations(**b**) (exemptions from charges: risks to health) is amended as follows.

(2) In paragraph (1)(b), omit "form".

Amendment of regulation 15 of the Charges Regulations

13.—(1) Regulation 15 of the Charges Regulations (certificates of exemption: application and issue) is amended as follows.

(2) For paragraph (1) substitute—

"(1) A person who wishes to claim exemption from charges payable under these Regulations ("an applicant") by virtue of—

(a) regulation 10(1)(d), (e) or (f), or a health care professional making such an application on an applicant's behalf, must apply for a certificate conferring exemption on an approved form provided by the Secretary of State; or

(b) regulation 10(1)(h), must apply for a certificate conferring exemption to the Ministry of Defence on an approved form provided by the Secretary of State.".

(3) In paragraph (2)—

(a) for "that mother's pregnancy, and in the case of a mother who gives birth" substitute "the period of twelve months beginning with the expected date of confinement, or in respect of applications received after an applicant has given birth"; and

(b) in sub-paragraph (a), after "the expected date of confinement" insert "or the date of birth (depending on which is requested)".

(4) After paragraph (2) insert—

"(2A) Where an exemption certificate is issued to an applicant who is an expectant mother the period of the validity of the certificate may be extended so that the twelve months is calculated from the child's date of birth if—

(a) that date is later than the expected date of confinement; and

(b) the mother requests such an extension following the birth of a child as mentioned in paragraph (2)(a) or (b).".

New regulation 15A of the Charges Regulations

14. After regulation 15 of the Charges Regulations (certificates of exemption: application and issue), insert—

"**Sharing of data relating to applications for medical and maternity exemption certificates**

15A.—(1) As regards any application made for an exemption certificate mentioned in regulation 15(1)(a) (either by the applicant or by a health care professional making an application on the applicant's behalf), paragraph (2) applies to the data (which may be electronic data) arising from—

(a) the completion of the application form (by whosoever completes it);

(**a**) 2002 c. 17. Section 25(3) had been amended by: the Health and Social Care Act 2008 (c. 14), Schedule 10, paragraph 17; the Health and Social Care Act 2012 (c. 7), Schedule 15, paragraph 56(b); the Children and Social Work Act 2017 (c. 16), Schedule 4, paragraph 2(2); and S.I. 2010/231.

(**b**) Amended by S.I. 2021/169.

(b) the processing of the application form for the purposes of assessing whether or not an applicant meets the entitlement criteria for the exemption certificate;

(c) the issuing of an exemption certificate to an applicant where it is appropriate to do so; and

(d) the management of these processes to ensure that they are performed effectively, efficiently and economically.

(2) Where paragraph (3) applies, the processing of data which is or is part of data described in paragraph (1) is—

(a) necessary for the performance of a task carried out in the public interest;

(b) the exercise of a function conferred on a person by an enactment (whether or not it would be so but for this sub-paragraph); and

(c) if the data is personal data concerning health, necessary for the management of health care systems or services.

(3) This paragraph applies where the processing—

(a) is by or on behalf of a relevant body or a provider of NHS services, including by another body on behalf of the relevant body or the provider of NHS services; and

(b) is for the purposes of performing, or facilitating the performance of, the functions mentioned in paragraph (1).

(4) A person who—

(a) is employed or engaged by a relevant body or provider of NHS services, or by a body processing data on their behalf as mentioned in paragraph (3)(a); and

(b) in the course of being so employed or engaged is required, for the purposes of performing, or facilitating the performance of, the functions mentioned in paragraph (1), to undertake the processing of data which is or is part of data described in that paragraph,

owes a duty of confidentiality in respect of that data (whether or not that person would do so but for this paragraph), but that duty is such that the person is able for those purposes, lawfully, to process that data by virtue of this regulation.

(5) Words and expressions used in both—

(a) paragraphs (2) to (4); and

(b) Parts 1 and 2 (preliminary and general processing) of, and paragraph 2(2)(f) of Schedule 1 (special categories of personal data and criminal convictions etc data – health or social care purposes) to, the Data Protection Act 2018(**a**),

bear the meanings they bear in those provisions of the Data Protection Act 2018.".

PART 4

Amendments to the National Health Service (General Medical Services Contracts) Regulations 2015 and the National Health Service (Personal Medical Services Agreements) Regulations 2015

Amendment of regulation 3 of the GMS Regulations

15.—(1) Regulation 3 of the GMS Regulations(**b**) (interpretation) is amended as follows.

(2) In paragraph (1)—

(**a**) 2018 c. 12.

(**b**) Amended by S.I. 2016/696 and 1077, 2018/844 and 1114, 2019/593, 1094 and 1137, 2020/226 and 351 and 2021/331 and 995.

(a) omit the definitions of "listed medicines" and "listed medicines voucher"; and

(b) at the appropriate places in the alphabetical order insert—

""listed prescription items" means the prescription items mentioned in regulation 13(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2015 (exemption from charges: risks to public health);"; and

""listed prescription items voucher" means a form which—

(a) is provided or approved by the Board for the purposes of ordering a prescription item mentioned in regulation 13(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2015; and

(b) may be an electronic form sent or to be sent via a secure service approved for this purpose by the Board;".

Amendment of regulation 55 of the GMS Regulations

16.—(1) Regulation 55 of the GMS Regulations(**a**) (prescribing: general) is amended as follows.

(2) In paragraph (1)(c), for "listed medicines" substitute "listed prescription items".

Amendment of regulation 56 of the GMS Regulations

17.—(1) Regulation 56 of the GMS Regulations(**b**) (orders for drugs, medicines or appliances) is amended as follows.

(2) In paragraph (3)—

(a) for "listed medicine", at each place where it occurs (four times), substitute "listed prescription item";

(b) for "listed medicines", at each place where it occurs (twice), substitute "listed prescription items"; and

(c) before "if one is used" insert "(with an electronic signature, if an electronic form is used)".

(3) In paragraph (4)—

(a) for "listed medicine", at each place where it occurs (four times), substitute "listed prescription item";

(b) for "listed medicines", at each place where it occurs (three times), substitute "listed prescription items"; and

(c) before "if one is used" insert "(with an electronic signature, if an electronic form is used)".

Amendment of regulation 61 of the GMS Regulations

18.—(1) Regulation 61 of the GMS Regulations (restrictions on prescribing by medical practitioners) is amended as follows.

(2) For "listed medicines", at each place where it occurs (twice), substitute "listed prescription items".

(3) In paragraph (3)(c)(ii), for "listed medicine" substitute "listed prescription item".

Amendment of regulation 62 of the GMS Regulations

19.—(1) Regulation 62 of the GMS Regulations (restrictions on prescribing by supplementary prescribers) is amended as follows.

(**a**) Amended by S.I. 2019/1137.
(**b**) Amended by S.I. 2018/1114.

(2) In paragraph (2)(c)(iii)(bb)—

(a) for "listed medicine" substitute "listed prescription item"; and

(b) for "medicine's" substitute "item's".

Amendment of regulation 3 of the PMS Regulations

20.—(1) Regulation 3 of the PMS Regulations(**a**) (interpretation) is amended as follows.

(2) In paragraph (1)—

(a) omit the definitions of "listed medicines" and "listed medicines voucher"; and

(b) at the appropriate places in the alphabetical order insert—

""listed prescription items" means the prescription items mentioned in regulation 13(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2015 (exemption from charges: risks to public health);"; and

""listed prescription items voucher" means a form which—

(a) is provided or approved by the Board for the purposes of ordering a prescription item mentioned in regulation 13(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2015; and

(b) may be an electronic form sent or to be sent via a secure service approved for this purpose by the Board;".

Amendment of regulation 48 of the PMS Regulations

21.—(1) Regulation 48 of the PMS Regulations(**b**) (prescribing: general) is amended as follows,

(2) In paragraph (1)(c), for "listed medicines" substitute "listed prescription items".

Amendment of regulation 49 of the PMS Regulations

22.—(1) Regulation 49 of the PMS Regulations(**c**) (orders for drugs, medicines or appliances) is amended as follows.

(2) In paragraph (3)—

(a) for "listed medicine", at each place where it occurs (four times), substitute "listed prescription item";

(b) for "listed medicines", at each place where it occurs (twice), substitute "listed prescription items"; and

(c) before "if one is used" insert "(with an electronic signature, if an electronic form is used)".

(3) In paragraph (4)—

(a) for "listed medicine", at each place where it occurs (four times), substitute "listed prescription item";

(b) for "listed medicines", at each place where it occurs (three times), substitute "listed prescription items"; and

(c) before "if one is used" insert "(with an electronic signature, if an electronic form is used)".

(**a**) Amended by S.I. 2016/696 and 1077, 2018/844 and 1114, 2019/593, 1094 and 1137, 2020/226 and 351 and 2021/331 and 995.

(**b**) Amended by S.I. 2019/1137.

(**c**) Amended by S.I. 2018/1114.

Amendment of regulation 54 of the PMS Regulations

23.—(1) Regulation 54 of the PMS Regulations (restrictions on prescribing by medical practitioners) is amended as follows.

(2) For "listed medicines", at each place where it occurs (twice), substitute "listed prescription items".

(3) In paragraph (3)(c)(ii), for "listed medicine" substitute "listed prescription item".

Amendment of regulation 55 of the PMS Regulations

24.—(1) Regulation 55 of the PMS Regulations (restrictions on prescribing by supplementary prescribers) is amended as follows.

(2) In paragraph (2)(c)(iii)(bb)—

(a) for "listed medicine" substitute "listed prescription item"; and

(b) for "medicine's" substitute "item's".

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

Maria Caulfield
Parliamentary Under Secretary of State,
Department of Health and Social Care

24th November 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 ("the 2006 Act"), for the provision of pharmaceutical and local pharmaceutical services. 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. They also amend the National Health Service (General Medical Services Contracts) Regulations 2015 ("the GMS Regulations") and the National Health Service (Personal Medical Services Agreements) Regulations 2015 ("the PMS Regulations"), which make provision in respect of the services provided in England under a general medical services contract and a personal medical services agreement made pursuant to Part 4 of the 2006 Act.

Each local authority Health and Wellbeing Board (HWB) has to publish a plan, known as a pharmaceutical needs assessment (PNA) for its area. The primary purpose of PNAs is to support pharmaceutical services commissioning decisions of the National Health Service Commissioning Board (now known as NHS England). Ordinarily, formal revisions of PNAs are published on a three year cycle, but preparation of revised PNAs had already been delayed because of the coronavirus pandemic. These Regulations amend the PLPS Regulations to further extend the deadline for HWBs to publish their revised PNAs from 1st April 2022 to 1st October 2022 (regulation 3(2)(b), (3) and (5)). However, HWBs established on or after 1st January 2022 are given 12 months from the date of their establishment to prepare their first PNA (regulation 3(2)(a), (4) and (5)). A consequential amendment is made to a provision relating to revising PNAs (regulation 3(6)). HWBs can, pending a formal revision of their PNA, issue supplementary statements on matters relevant to NHS England's commissioning decisions – if this is essential to prevent significant detriment to pharmaceutical services provision in their area. These Regulations allow new HWBs to issue supplementary statements updating the PNAs they inherit from the HWBs they replace, pending the publication of the new HWB's own first PNA (regulation 3(7)). Any supplementary statements that the old or new HWBs have issued then become part of the PNA that NHS England uses to support commissioning decisions that relate to the area of the new HWB – and a spent provision about Primary Care Trust PNAs is omitted (regulation 4).

Where a retail pharmacy business or a dispensing appliance contractor wishes to apply for new premises in the area of a HWB based on gaps or improvements identified in the HWB's PNA,

they may make what is known as a "routine application" to NHS England. Such applications allow the applicant, for example, to offer to open on days or at times when the PNA indicates there could be better access to what are known as "essential services", which are the core pharmaceutical services that include dispensing services. Amendments made by these Regulations to the PLPS Regulations require NHS England to turn down routine applications that, in essence, offer better access to essential services via extended or different opening hours, if NHS England are satisfied that granting the application would lead to an undesirable increase in the availability of essential services in the area of the HWB (regulation 5).

Retail pharmacy businesses and dispensing appliance contractors, as well as providing the pharmaceutical services that they are required to provide (as set out, in particular, in respectively Schedules 4 and 5 to the PLPS Regulations), may also provide what are known as "additional pharmaceutical services" – provision for which is made in directions under section 127 of the 2006 Act. The additional pharmaceutical services that NHS England are authorised, as opposed to required, to commission are known as "enhanced services". Historically, the expectation has been that these services will be commissioned on the basis of locally agreed terms and conditions, and consultation on the terms of remuneration has been required with the Local Pharmaceutical Committee of the area in which the service is to be provided. However, if these "enhanced services" are to be based on standard conditions set nationally, consultation will need instead to be with a body that represents the interests of retail pharmacy businesses or, as the case may be, dispensing appliance contractors nationally (regulation 6).

There are a number of different ways in which pandemic treatments may be ordered for and supplied to NHS patients in England. Two of the routes to supply – pandemic treatment protocols (PTPs) and pandemic treatment patient group directions (PTPGDs) – do not require a treatment decision by an authorised prescriber, who might in ordinary circumstances be a general practitioner (GP). If the supply is to be made by a retail pharmacy business (and so at or from a community pharmacy), it is possible that arrangements may be made for that supply either as part of essential services or as part of additional pharmaceutical services. These Regulations amend the PLPS Regulations to provide that where arrangements are in place for the supply of pandemic treatments under PTPs or PTPGDs as part of additional pharmaceutical services, they are to be supplied on the basis of those arrangements and not by community pharmacies as part of essential services or by dispensing doctors (GPs in rural areas that supply prescription items to those of their registered patients to whom they are entitled to provide dispensing services) (regulation 7 and 9(2)).

An alternative route to supply of pandemic treatments is via a listed prescription items voucher (LPIV). These may be in an electronic form and can be used for the free supply of prescription items, the supply of which is for or in anticipation of pandemic disease, or for certain other emergency situations. If these prescription items are prescription only medicines, the LPIV will be a prescription of an authorised prescriber – but in all cases, although they will be issued under NHS arrangements, they will not be one of the ordinary forms of NHS prescriptions. If a community pharmacy receives an LPIV, amendments to the PLPS Regulations made by these Regulations require the community pharmacy to dispense the prescription item as part of essential services, as it would an ordinary NHS prescription – unless arrangements are in place for the LPIV to be dispensed as part of additional pharmaceutical services, in which case it is only to be dispensed as part of additional pharmaceutical services. Arrangements are also made so that dispensaries of dispensing doctors are also able to supply prescription items against LPIVs unless they are instead to be supplied as part of additional pharmaceutical services (regulations 2, 7, 9 and 10).

Amendments are also made to the GMS and PMS Regulations, and a consequential amendment made to the Charges Regulations (regulation 12), that are related to these LPIV changes. Arrangements were already in place under the GMS Regulations and PMS Regulations for authorised prescribers at GP practices to order medicines on vouchers, before now described as "listed medicines vouchers" – the relevant list being the medicines mentioned in regulation 13(1) of the Charges Regulations, which relates to the free supply of pandemic treatments and treatments needed in certain other emergency situations. These Regulations amend the GMS Regulations and the PMS Regulations to update those references to take account of the fact that

the arrangements for free supply could now be for prescription items that are not medicines (and so listed medicines vouchers have become LPIVs). These Regulations also amend the GMS Regulations and the PMS Regulations to take account of the fact that the vouchers could be electronic vouchers (regulations 15 to 24).

Those community pharmacies whose terms of service are principally set out in Schedule 4 to the PLPS Regulations are, as part of those terms of service, required to have in place arrangements for clinical governance and the promotion of healthy living, which includes a number of programmes. These Regulations update those arrangements so that in future the programmes will include, if NHS England requests that they do, a pandemic response programme with specified elements (regulation 8).

These Regulations also amend the Charges Regulations to include new provisions in respect of medical and maternity exemption certificates. There is a new statutory information gateway to support the claiming and provision of such certificates, and the management of those processes (regulation 14). The provisions relating to the making of claims for exemption certificates are amended so that applications can be made either by a person claiming exemption or a health care professional acting on their behalf – and removing a reference to a named form. Arrangements relating to live and still births are substantially aligned, and mothers who applied for their certificate before their child was born (including those whose child was still born) may apply for extensions to their certificates if the date of birth is later than the expected date of confinement (regulation 13).

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