STATUTORY INSTRUMENTS

2020 No. 1126

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020

Made - - - - 16th October 2020

Laid before Parliament 19th October 2020

Coming into force in accordance with regulation 1(2) to (4)

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(**1**).

PART 1

Introductory

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020.

(2) Subject to paragraphs (3) and (4), these Regulations come into force on the twenty-first day after the day on which they are laid before Parliament.

(3) Regulations 12, 14 and 15(1) come into force on 1st January 2021.

(4) Regulation 15(2) comes into force on 1st April 2021.

(**1**) 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". By virtue of section 271(1) of the 2006 Act, the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England.

(5) In these Regulations, "the PLPS Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**2**).

PART 2

Amendment of Part 1 of the PLPS Regulations

Amendment of regulation 2 of the PLPS Regulations

2. In regulation 2(1) of the PLPS Regulations(**3**) (interpretation)—

(a) at the appropriate places insert—

""financial year" means the 12 months ending with 31st March;";

""NHS Digital directory of services" means the directory of services, maintained by the Information Centre, which is accessed by NHS urgent and emergency care services if a patient is in need of urgent assistance from a health care professional or urgent access to health care advice;"; and

""NHSmail" means the secure e-mail service of that name for the sharing of patient identifiable and patient sensitive information, for which the Information Centre is responsible;"; and

(b) at the appropriate place insert—

""PTP" means a pandemic treatment protocol, which is a protocol—

(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) approved in accordance with regulation 247 of the Human Medicines Regulations 2012(**4**) (exemption for supply in the event or anticipation of pandemic disease);".

PART 3

Amendment of Part 9 of the PLPS Regulations

New regulation 67A of the PLPS Regulations

3. After regulation 67 of the PLPS Regulations (conditions relating to voluntary closure of premises), insert—

"**Condition relating to entering administration**

67A.—(1) An NHS chemist must, if the NHS chemist enters administration, notify the NHSCB of that fact.

(2) For these purposes, "enters administration" has the meaning given in paragraph 1(2)(b) of Schedule B1 to the Insolvency Act 1986(**5**) (administration).".

(**2**) S.I. 2013/349, as amended.
(**3**) 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.
(**4**) S.I. 2012/1916; regulation 247 has been amended by S.I. 2013/235 and 2020/1125.
(**5**) Schedule B1 was inserted by the Enterprise Act 2002 (c. 40), Schedule 16.

PART 4

Amendment of Schedule 2 to the PLPS Regulations

Amendment of paragraph 34 of Schedule 2 to the PLPS Regulations

4. In Schedule 2 to the PLPS Regulations (applications in respect of pharmaceutical lists and the procedures to be followed), in paragraph 34(**6**) (taking effect of decisions: general)—

(a) in sub-paragraph (2), omit "in the next 14 days"; and

(b) after sub-paragraph (3), insert—

"(3A) A notice of commencement is invalid unless it is given to the NHSCB no fewer than 30 days prior to the date on which the provision of services is to commence, unless prior to the notified date the NHSCB has agreed with P a shorter period of prior notice.

(3B) P must notify the NHSCB in writing as soon as reasonably practicable of any change to the date included in a notice of commencement as the date on which the provision of services is to commence, and must do so in advance of both dates.".

PART 5

Amendment of Schedule 4 to the PLPS Regulations

Amendment of Schedule 4 to the PLPS Regulations

5. Schedule 4 to the PLPS Regulations (terms of service of NHS pharmacists) is amended in accordance with this Part.

New paragraph 5B

6. After paragraph 5A(**7**) (supply in accordance with a SSP) insert—

"**Supply in accordance with a PTP**

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

(a) an NHS Pharmacist (P) receives, via a secure service approved by the NHSCB for this purpose, an electronic message that amounts to an order for the supply of a drug in accordance with a PTP; and

(b) a person who is entitled to be supplied with that drug in pursuance of that order requests the provision of the drug in accordance with that order,

P must, with reasonable promptness, provide the drug 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 drug will be ready; and

(b) if they are not ready by then, P must give a revised estimate of the time when they will be ready (until they are ready).".

(**6**) Paragraph 34 has been amended by S.I. 2016/1077.
(**7**) Paragraph 5A was inserted by S.I. 2019/990.

Amendment of paragraph 8

7. In paragraph 8(**8**) (providing ordered drugs or appliances)—

(a) in sub-paragraph (15), after "paragraph 5A" insert "or 5B"; and

(b) after sub-paragraph (16) insert—

"(17) Sub-paragraphs (5) to (10) apply to the provision of a drug in accordance with a PTP as they apply to the provision of a drug in accordance with a prescription form or a repeatable prescription (or an associated batch issue).

(18) Where P provides a drug under paragraph 5B, P must include a dispensing label on the packaging of the product and include in the label (in addition to the particulars required or permitted by Part 2 of Schedule 26 to the Human Medicines Regulations 2012), for the patient's benefit, information to the effect that the product is being supplied in accordance with a PTP, identifying the particular PTP.".

Amendment of paragraph 9

8. In paragraph 9(**9**) (refusal to provide drugs or appliances ordered)—

(a) in sub-paragraph (2A), after "(or at all)" insert—

", but where P does so, P must take all reasonable steps to ensure that the product ordered by the prescriber is supplied within a reasonable timescale, which may include (depending on what steps or combination of steps the circumstances require)—

(a) providing details of other NHS pharmacists or LPS chemists whose premises are situated in the same area and who may be able to provide the product ordered by the prescriber;

(b) urgent supply without a prescription in accordance with paragraph 6;

(c) arranging for the urgent provision of a non-electronic prescription form by the prescriber."; and

(b) after sub-paragraph (4) insert—

"(5) P may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP where—

(a) P reasonably believes it is not a genuine order for the person who requests, or on whose behalf is requested, the provision of the drug;

(b) providing it would be contrary to P's clinical judgement;

(c) P or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying that person; or

(d) the person who requests the provision of the drug, or any person accompanying that person, commits or threatens to commit a criminal offence.

(6) P must refuse to provide, pursuant to a PTP, an order for a drug that is or is purportedly in accordance with the PTP where P is not satisfied that it is in accordance with the PTP.".

(**8**) Amended by S.I. 2019/990.
(**9**) Amended by S.I. 2018/1114 and 2019/990.

Amendment of paragraph 10

9. In paragraph 10(**10**) (further activities to be carried out in connection with the provision of dispensing services), in sub-paragraph (1)—

(a) in paragraph (e), after "written note" insert "(which may be in an electronic form)"; and

(b) omit paragraph (g).

Amendment of paragraph 11

10. In paragraph 11(**11**) (additional requirements in relation to electronic prescribing)—

(a) in sub-paragraph (1)—

(i) omit paragraph (a), and

(ii) in paragraph (b), for "not available" substitute "temporarily unavailable"; and

(b) in sub-paragraph (2), omit "Where the Electronic Prescription Service is available through P's premises,".

Amendment of paragraph 18

11.—(1) Paragraph 18 (health campaigns) is amended as follows.

(2) Omit "public" from its heading.

(3) In paragraph (a)—

(a) for "calendar" substitute "financial"; and

(b) omit "public".

(4) At the end of sub-paragraph (b) insert "; and".

(5) After sub-paragraph (b) insert—

"(c) where requested to do so by the NHSCB, P sends to the NHSCB by means of an electronic communication of the type specified in the request—

(i) the number recorded pursuant to sub-paragraph (b), and

(ii) information which is reasonably requested by the NHSCB, and which is in an anonymised form if it would otherwise identify any person to whom information was provided as part of the campaign, for the purposes of evaluating the effectiveness of the campaign and policy development.".

New paragraphs 22B and 22C

12. In Part 2 (essential services), after paragraph 22A(**12**) (home delivery service while a disease is or in anticipation of a disease being imminently pandemic etc.) insert—

"**Discharge medicines service**

22B. An NHS pharmacist (P) must, to the extent that paragraph 22C requires and in the manner set out in that paragraph, provide advice, assistance and support to and in respect of a health service patient—

(**10**) Amended by S.I. 2015/58 and 2019/990
(**11**) Amended by S.I. 2018/1114.
(**12**) Inserted by S.I. 2020/351.

(a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or

(b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

Service outline in respect of the discharge medicines service

22C.—(1) An NHS pharmacist (P) must have procedures in place (as part of its standard operating procedures) for checking at appropriate intervals on days on which P's pharmacy premises are open for business whether P has received any referrals, which are in the form and manner approved for this purpose by the NHSCB, for the services set out in this paragraph ("DMS referrals").

(2) If P receives a DMS referral in respect of a health service patient (X) requesting from P stage 1 of the service (as well as stages 2 and 3), P must, as soon as possible but in any event within 72 hours of receiving the DMS referral (excluding hours of days on which the pharmacy premises are not open for business), as stage 1 of the service—

(a) review the actions requested, and act on those requested actions, to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so;

(b) use the information that P has or is able to access about X's medication regimen before the discharge or transfer to compare it (so far as is possible) with X's medication regimen on discharge or transfer;

(c) check any prescriptions for X that P may be asked to dispense (including electronic repeatable prescriptions) or has part dispensed in order to assess whether, in P's clinical judgement, any changes are appropriate or there are any other issues of concern;

(d) where necessary, discuss changes that may be appropriate or raise any issues of concern identified, to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so with—

(i) the staff of the hospital or other provider of NHS services that made the referral, and

(ii) any provider of primary medical services on whose patient list X is; and

(e) keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stages 2 and 3 of the service).

(3) This sub-paragraph applies—

(a) if P receives—

(i) in respect of X an electronic prescription for a medicinal product or is presented by X with a non-electronic prescription form, a non-electronic repeatable prescription or an EPS token in respect of a medicinal product, and

(ii) is on notice as a result of a DMS referral requesting from P stage 2 of the service (whether or not it is the referral mentioned in sub-paragraph (2)) that the prescription is the first prescription for a medicinal product to be dispensed by P to X following X's discharge from hospital or the transfer of X's care between different providers of NHS services; or

(b) in the following circumstances—

(i) P receives in respect of a health service patient (Y) an electronic prescription for a medicinal product or is presented by Y with a non-electronic prescription form, a non-electronic repeatable prescription or an EPS token in respect of a medicinal product,

(ii) P is on notice as a result of a DMS referral requesting from P stage 2 of the service (and potentially stage 3) that it is the first prescription for a medicinal product to be dispensed to Y following Y's discharge from hospital or the transfer of Y's care between different providers of NHS services (a different NHS pharmacist having provided stage 1 of the service in respect of Y), and

(iii) P is on notice that Y, or where appropriate a carer of Y, wishes P to provide the services described in sub-paragraphs (4) and (5) to or in respect of Y.

(4) Where sub-paragraph (3) applies, P must, as stage 2 of the service, prior to or as part of the process of dispensing the prescription—

(a) review (or further review) the medication regimen of X or Y, using the information that P has or is able to access about that medication regimen, including from the prescription, in order to assess whether, in P's clinical judgement, appropriate account has been taken of any changes to X's or Y's medication regimen during X's or Y's stay in hospital or prior to the transfer of X's or Y's care between different providers of NHS services;

(b) if any issues of concern are identified, raise these to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so with any provider of primary medical services on whose patient list X or Y is; and

(c) keep and maintain records of any actions taken as part of this stage of the process, as appropriate (in particular, to support delivery of stage 3 of the service).

(5) At the point at which P, in P's clinical judgement is to, or would normally, discuss the prescription as mentioned in paragraph (3)(a)(i) or (b)(i) with X or Y, or where appropriate with a carer of X or Y, P must, as stage 3 of the service—

(a) engage in a discussion with X or Y, or where appropriate a carer of X or Y, in a manner which is in accordance with P's duty of confidentiality to X or Y and which is—

(i) to assess their understanding of what medicinal products X or Y should be taking, and

(ii) to offer to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so advice, assistance and support in respect of X's or Y's medication regimen;

(b) draw to X's or Y's attention (where appropriate via a carer of X or Y)—

(i) P's disposal service in respect of unwanted drugs, and

(ii) any other pharmaceutical services that P, in the exercise of P's clinical judgement, considers X or Y may benefit from following X's or Y's stay in hospital or the transfer of X's or Y's care between different providers of NHS services;

(c) if any issues of concern are identified, raise these to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so with any provider of primary medical services on whose patient list X or Y is; and

(d) keep and maintain records, as appropriate—

(i) of the discussion pursuant to paragraphs (a) and (b), and of any raising of concerns and any actions taken, and

(ii) for service evaluation purposes.

(6) If the DMS referral requesting that P provides services under this paragraph includes circumstances in which P is not to provide, or is to cease to provide, services under this paragraph, P is not to, or is to cease to, provide services under this paragraph in those circumstances (for example, X's or Y's admission or re-admission to hospital).".

New paragraph 27B

13. After paragraph 27A(**13**) (pharmacy opening hours: arrangements while a disease is or in anticipation of a disease being imminently pandemic etc.) insert—

"**Flexible provision of relevant immunisation services during a pandemic etc.**

27B.—(1) Notwithstanding the forgoing provisions of this Part, in order to assist in the management of a serious risk or potentially serious risk to human health which arises as a consequence of a disease being, or in anticipation of a disease being imminently, pandemic, an NHS pharmacist (P) may, with the agreement of the NHSCB, limit for a specified period (within P's core and supplementary opening hours) the pharmaceutical services provided at or from P's pharmacy premises to relevant immunisation services.

(2) If the NHSCB has made an announcement to the effect that there are particular arrangements under this paragraph that it is prepared to agree, and P limits P's provision of pharmaceutical services to relevant immunisation services in a manner that is consistent with that announcement, it is to be assumed (in the absence of a contrary notification from the NHSCB to P) that P has the agreement of the NHSCB to those arrangements.

(3) In this paragraph, "relevant immunisation services" means directed services that provide for the administration of a medicinal product for vaccination or immunisation against coronavirus or influenza virus in accordance with—

(a) a patient group direction that meets the conditions of regulation 233 of the Human Medicines Regulations 2012(**14**) (exemption for supply etc under a PGD by a person conducting a retail pharmacy business); or

(b) a protocol that meets the conditions of regulation 247A of the Human Medicines Regulations 2012(**15**) (protocols relating to coronavirus and influenza vaccinations and immunisations),

and for these purposes, "coronavirus" has the meaning given in section 1(1) of the Coronavirus Act 2020(**16**).".

Amendment of paragraph 28

14.—(1) Paragraph 28(**17**) (clinical governance) is amended as follows.

(2) In its heading, after "clinical governance" insert "and the promotion of healthy living".

(3) In paragraph (1), after "clinical governance" insert "and for the promotion of healthy living".

(4) In paragraph (2)—

(a) after "clinical governance" at the first place where it occurs, insert "and for the promotion of healthy living";

(**13**) Inserted by S.I. 2020/351.
(**14**) S.I. 2012/1919; the relevant amending instruments are S.I. 2013/235, 2015/1503, 2019/775 and 2020/1125.
(**15**) Inserted by S.I. 2020/1125.
(**16**) 2020 c. 7.
(**17**) Amended by S.I. 2015/58 and 2016/1077.

(b) in sub-paragraph (a)—

(i) omit "and" at the end of paragraph (vi),

(ii) insert "and" at the end of paragraph (vii), and

(iii) after paragraph (vii), insert—

"(viii) undertaking at least once in each financial year an approved community engagement exercise in relation to the promotion of healthy living.";

(c) in sub-paragraph (c)(v), after "in respect of" insert "the discharge medicines service";

(d) in sub-paragraph (e)(iv), for "in respect of the provision of directed services" substitute ", certification or declarations of competence in respect of any role they are asked to perform"; and

(e) in sub-paragraph (g)(ii), after "receive health care" insert "and for the promotion of healthy living".

New paragraphs 28A to 28C

15.—(1) After paragraph 28 (clinical governance and the promotion of healthy living) insert—

"**Premises requirements in respect of consultation rooms**

28A.—(1) An NHS pharmacist must ensure that at pharmacy premises, other than distance selling premises, there is a consultation room which is—

(a) clearly designated as a room for confidential conversations;

(b) distinct from the general public areas of the pharmacy premises; and

(c) a room where both a person accessing pharmaceutical services and a person performing pharmaceutical services are able to be seated together and communicate confidentially.

(2) Where, in the opinion of the NHSCB, pharmacy premises other than distance selling premises included on a pharmaceutical list on the relevant day are too small for a consultation room—

(a) the NHS pharmacist in respect of those premises may, with the agreement of the NHSCB, comply with paragraph 28B instead of sub-paragraph (1); and

(b) for these purposes, references to distance selling premises in paragraph 28B are to be treated as a reference to the premises about which the NHSCB has formed the opinion that they are too small for a consulting room.

(3) An NHS pharmacist in respect of premises that were on a pharmaceutical list on the relevant day but no advanced services were provided at or from those premises during the year before the relevant day need not comply with sub-paragraphs (1) or (2) in respect of those premises before 1st April 2023.

(4) In this paragraph, "the relevant day" means the day of the coming into force of regulation 15(1) of the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020.

Consultations held from distance selling premises and some small pharmacy premises

28B. An NHS pharmacist in respect of distance selling premises must ensure that there are arrangements in place at those premises which enable a person performing pharmaceutical services to communicate confidentially with a person accessing pharmaceutical services—

(a) by telephone or another live audio link; and

(b) via a live video link.".

(2) After paragraph 28B insert—

"**Distance selling premises requirements in respect of websites and health promotion zones**

28C. An NHS pharmacist (P) in respect of distance selling premises must ensure that P has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.".

Amendment of paragraph 29A

16. In paragraph 29A(**18**) (accessing summary care records), for sub-paragraphs (1) and (2) substitute—

"(1) An NHS pharmacist (P) must have access to summary care records at P's pharmacy premises, and must ensure that the access that P has to summary care records at those premises is constant and reliable during core and supplementary opening hours, in so far as that is within the control of P.

(2) P must access the summary information in a patient's summary care record whenever P is providing pharmaceutical services to the patient, to the extent that P, in the exercise of P's clinical judgement, considers it appropriate to do so.".

New paragraphs 29B and 29C

17. After paragraph 29A (accessing summary care records) insert—

"**Electronic Prescription Service access**

29B. An NHS pharmacist (P) must have access to the EPS at P's pharmacy premises, and must ensure that the access that P has to the EPS at those premises is constant and reliable during core and supplementary opening hours, in so far as that is within the control of P.

Contact via NHSmail, pharmacy profiles and the Central Alerting System

29C.—(1) An NHS pharmacist (P) must ensure that pharmacy staff at pharmacy premises (including locums) have access to, and are able to send and receive NHSmail from, a premises specific NHSmail account.

(2) P must ensure that at least two members of the pharmacy staff have live, linked NHSmail accounts to the premises specific NHSmail account (unless fewer than two members of the pharmacy staff are engaged in the provision of NHS services).

(3) P must ensure that there is a comprehensive and accurate pharmacy profile in respect of P's pharmacy premises in the NHS Digital directory of services, and P must verify and where necessary update the information contained in that profile at least once each quarter of the financial year.

(4) P must ensure that there is a comprehensive and accurate pharmacy profile in respect of P's pharmacy premises on the NHS.uk website, and P must verify and where necessary update the information contained in that profile at least once each quarter of the financial year.

(**18**) Inserted by S.I. 2016/296.

(5) As regards the Central Alerting System (CAS) operated by the Medicines and Healthcare products Regulatory Agency(**19**) (MHRA)—

(a) P must register P's premises specific NHSmail address with MHRA as an address at which P is content to accept notifications as part of the CAS (unless they are content with the address already in the system);

(b) if P changes P's premises specific NHSmail address, P must immediately notify MHRA of P's new premises specific NHSmail address, in accordance with paragraph (a); and

(c) P must monitor P's premises specific NHSmail account with sufficient frequency to ensure the safe and effective supply of medicinal products at or from P's pharmacy premises, and must act on the alerts P receives as part of the CAS, as appropriate.".

New paragraph 32A

18. After paragraph 32 (other information to be supplied) insert—

"**Facilitating remote access to pharmaceutical services**

32A.—(1) An NHS pharmacist (P) must, to the extent reasonable—

(a) facilitate remote access to the pharmaceutical services provided at or from P's pharmacy premises, where users wish to access those services under arrangements that make those services available using remote access; and

(b) establish, maintain and keep under review procedures to facilitate remote access to those services under arrangements that make those services available using remote access.".

Amendment of paragraph 35

19. In paragraph 35 (inspections and access to information), after sub-paragraph (3) insert—

"(4) P must, at the request of the NHSCB, send to the NHSCB by means of an electronic communication of the type specified in the request any information to which a person authorised in writing by the NHSCB would have access during an inspection of P's pharmacy premises pursuant to sub-paragraph (1), if—

(a) P has that information in a form which means it may be sent by that form of electronic communication; or

(b) it is reasonable for the NHSCB to request that P convert that information into a form which means that it may be sent by that form of electronic communication (and the NHSCB does so request).

(5) P must, at the request of NHSCB or a person authorised in writing by the NHSCB to make the request, send to the NHSCB or that person by means of an electronic communication, a duly completed questionnaire, which is—

(a) in a format approved by the NHSCB; and

(b) for the purpose of enabling NHSCB, or a person authorised in writing by the NHSCB, to determine whether or when it is necessary or expedient for a person authorised in writing by the NHSCB to undertake an inspection of P's premises pursuant to sub-paragraph (1).

(**19**) The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health and Social Care. Its address is 10 South Colonnade, Canary Wharf, London E14 4PU.

(6) Before information is requested pursuant to sub-paragraph (5), the NHSCB must consult the person who is, for the time being, the person consulted under section 165(1)(a) of the 2006 Act, in respect of pharmaceutical remuneration of NHS pharmacists on the terms of the request.".

PART 6

Amendment of Schedule 6 to the PLPS Regulations

Amendment of Schedule 6 to the PLPS Regulations

20. Schedule 6 to the PLPS Regulations (terms of service of dispensing doctors) is amended in accordance with this Part.

New paragraph 3B

21. After paragraph 3A(**20**) (supply in accordance with a SSP) insert—

"**Supply in accordance with a PTP**

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

(a) a dispensing doctor (D) receives, via a secure service approved by the NHSCB for this purpose, an electronic message that amounts to an order for the supply of a drug in accordance with a PTP; and

(b) a person who is entitled to be supplied with that drug in pursuance of that order requests the provision of the drug in accordance with that order,

D must, with reasonable promptness, provide the drug so ordered.

(2) If a person requesting the provision of the drug asks D to do so—

(a) D must give an estimate of the time when the drug will be ready; and

(b) if they are not ready by then, D must give a revised estimate of the time when they will be ready (until they are ready).

(3) Where D provides a drug under sub-paragraph (1), D must include a dispensing label on the packaging of the product and include in the label (in addition to the particulars required or permitted by Part 1 of Schedule 26 to the Human Medicines Regulations 2012), for the patient's benefit, information to the effect that the product is being supplied in accordance with a PTP, identifying the particular PTP.".

Amendment of paragraph 6

22. In paragraph 6(**21**) (refusal to provide drugs or appliances ordered), after sub-paragraph (4) insert—

"(5) D may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP where—

(a) D reasonably believes it is not a genuine order for the person who requests, or on whose behalf is requested, the provision of the drug;

(b) providing it would be contrary to D's clinical judgement;

(**20**) Paragraph 3A was inserted by S.I. 2019/990.
(**21**) Paragraph 6 has been amended by S.I. 2018/1114 and 2019/990.

(c) D or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying that person; or

(d) the person who requests the provision of the drug, or any person accompanying that person, commits or threatens to commit a criminal offence.

(6) D must refuse to provide, pursuant to a PTP, an order for a drug that is or is purportedly in accordance with the PTP where D is not satisfied that it is in accordance with the PTP.".

PART 7

Amendment of Schedule 7 to the PLPS Regulations

Amendment of Schedule 7 to the PLPS Regulations

23. Schedule 7 to the PLPS Regulations (mandatory terms for LPS schemes) is amended in accordance with this Part.

Amendment of paragraph 7

24. In paragraph 7(**22**) (refusal to provide drugs or appliances ordered), in sub-paragraph (2A), after "(or at all)" insert—

", but where C does so, C must take all reasonable steps to ensure that the product ordered by the prescriber is supplied within a reasonable timescale, which may include (depending on what steps or combination of steps the circumstances require)—

(a) providing details of other LPS chemists or NHS pharmacists whose premises are situated in the same area and who may be able to provide the product ordered by the prescriber;

(b) urgent supply without a prescription in accordance with paragraph 4;

(c) arranging for the urgent provision of a non-electronic prescription form by the prescriber.".

Amendment of paragraph 8

25. In paragraph 8 (further activities to be carried out in connection with the provision of dispensing services), in sub-paragraph (1)(c), after "written note" insert "(which may be in an electronic form)".

Amendment of paragraph 9

26. In paragraph 9(**23**) (additional requirements in relation to electronic prescribing)—

(a) in sub-paragraph (1)—

(i) omit paragraph (a), and

(ii) in paragraph (b), for "not available" substitute "temporarily unavailable"; and

(b) in sub-paragraph (2), omit "Where the Electronic Prescription Service is available through C's premises ,".

(**22**) Paragraph 7 has been amended by S.I. 2018/1114 and 2019/990.
(**23**) Amended by S.I. 2018/1114.

Amendment of paragraph 13A

27. In paragraph 13A(**24**) (accessing summary care records), for paragraphs (1) and (2) substitute—

"(1) An LPS chemist (C) must have access to summary care records at C's scheme premises, and must ensure that the access that C has to summary care records at those premises is constant and reliable during the hours when the scheme premises are open to the public, in so far as that is within the control of C.

(2) C must access the summary information in a patient's summary care record whenever C is providing local pharmaceutical services to the patient, to the extent that C, in the exercise of C's clinical judgement, considers it appropriate to do so.".

New paragraphs 13B and 13C

28. After paragraph 13A (accessing summary care records) insert—

"**Electronic Prescription Service access**

13B. An LPS chemist (C) must have access to the EPS at C's scheme premises, and must ensure that the access that C has to the EPS at those premises is constant and reliable during the hours when the scheme premises are open to the public, in so far as that is within the control of C.

Contact via NHSmail and the Central Alerting System

13C.—(1) An LPS chemist (C) must ensure that pharmacy staff at listed premises (including locums) have access to, and are able to send and receive NHSmail from, a premises specific NHSmail account.

(2) C must ensure that at least two members of the pharmacy staff have live, linked NHSmail accounts to the premises specific NHSmail account (unless fewer than two members of the pharmacy staff are engaged in the provision of NHS services).

(3) As regards the Central Alerting System (CAS) operated by the Medicines and Healthcare products Regulatory Agency(**25**) (MHRA)—

(a) C must register C's premises specific NHSmail address with MHRA as an address at which C is content to accept notifications as part of the CAS (unless they are content with the address already in the system);

(b) if C changes C's premises specific NHSmail address, P must immediately notify MHRA of C's new premises specific NHSmail address, in accordance with paragraph (a); and

(c) C must monitor C's premises specific NHSmail account with sufficient frequency to ensure the safe and effective supply of medicinal products at or from C's pharmacy premises, and must act on the alerts C receives as part of the CAS, as appropriate.".

(**24**) Inserted by S.I. 2016/296.

(**25**) The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health and Social Care. Its address is 10 South Colonnade, Canary Wharf, London E14 4PU.

PART 8

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

New regulation 13B of the National Health Service (Charges for Drugs and Appliances) Regulations 2015

29. After regulation 13A of the National Health Service (Charges for Drugs and Appliances) Regulations 2013(**26**) (exemption from charges: supply of a smaller quantity of a product in accordance with a SSP) insert—

"**Coronavirus and influenza vaccinations and immunisations**

13B.—(1) No charge is payable under these Regulations in respect of the supply or administration to an eligible person of a medicinal product used for vaccination or immunisation against coronavirus or influenza virus.

(2) In this regulation—

"coronavirus" has the meaning given in section 1(1) of the Coronavirus Act 2020(**27**); and

"eligible person" means a person who is of a class or description that means they would be entitled to be supplied with the medicinal product, or have it administered to them, in accordance with—

(a) a national patient group direction under regulation 233 of the Human Medicines Regulations 2012(**28**) (exemption for supply etc under a PGD by a person conducting a retail pharmacy business), signed on behalf of the Board in accordance with paragraph (5)(a) of that regulation; or

(b) a national protocol under regulation 247A of the Human Medicines Regulations 2012(**29**) (protocols relating to coronavirus and influenza vaccinations and immunisations) approved by the Secretary of State,

whether or not the medicinal product is supplied or administered to that person in accordance with such a patient group direction or protocol.".

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

Jo Churchill
Parliamentary Under-Secretary of State,
Department of Health and Social Care

16th October 2020

(**26**) S.I. 2015/570; regulation 13A was inserted by S.I. 2019/990.
(**27**) 2020 c. 7.
(**28**) Regulation 233 has been amended by S.I. 2013/235, 2015/1503, 2019/775 and 2020/1125.
(**29**) Inserted by S.I. 2020/1125.

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 National Health Service ("NHS") terms of service of four different types of provider: retail pharmacy businesses on pharmaceutical lists held by the NHS Commissioning Board (known as "pharmacy contractors"); dispensing appliance contractors (known as "DACs"); dispensing doctors; and the 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 include measures that are part of the response to the coronavirus pandemic, related to which is the expansion of the national programme for immunisation against influenza. The Charges Regulations are amended to ensure that all coronavirus and influenza immunisations administered by NHS providers to eligible patients are to be supplied free of charge (regulation 29). Pharmacy contractors may, with the agreement of the NHS Commissioning Board and for a specified period, limit the NHS pharmaceutical services provided at pharmacies to the administration of vaccinations or immunisations against coronavirus and influenza (regulation 13). Provision is also made so that pharmacy contractors and dispensing doctors are required to supply against so-called "pandemic treatment protocols", which allow for the supply, without a prescription, of prescription only medicines used for the prevention or treatment of diseases that are, or in anticipation of them being imminently, pandemic. There are supplementary provisions related to this requirement dealing with matters such as dispensing labels (regulations 2(b), 6, 7, 8(b) and 20 to 22).

These Regulations also include a number of service developments, in particular for pharmacy contractors. Pharmacy contractors are required to facilitate remote access to their services (regulation 18), and pharmacy contractors and LPS contractors are required to have, and to have constant and reliable access to, the Electronic Prescription Service (the system used for the transmission of electronic prescriptions between different providers of the NHS primary care services) when they are open for business – in so far as this is within their control (regulations 17 and 28). There are also measures to deal with circumstances when the system is temporarily unavailable (regulations 8(a), 10, 24 and 26). Pharmacy contractors and LPS contractors are also required to have, and to have constant and reliable access to, a networked system of NHS patient summary care records (regulation 16 and 27), and a premises specific NHSmail account – generally with two live NHSmail accounts for their staff. They must also register with and use the Central Alerting System operated by the Medicines and Healthcare products Regulatory Agency. Additionally, pharmacy contractors must have comprehensive and accurate pharmacy profiles in the NHS Digital directory of services and on the NHS.uk website (regulations 2(a), 17 and 28). Also, where pharmacy contractors and LPS contractors are unable to supply a prescription item immediately and instead provide a note of the item that is owed, this may be in an electronic instead of a paper form (regulations 9(a) and 25).

Separately, pharmacy contractors existing obligations in relation to public health campaigns are revised so that the campaigns can relate, more broadly, to health issues – and so as to support service evaluation and policy development (regulations 2(a) and 11). Their clinical governance requirements are also amended, in particular to allow those to accommodate the promotion of healthy living, and

around training and certification (regulation 14). Distance selling pharmacies are also required to have a health promotion zone on their website (regulation 15).

The most significant change for pharmacy contractors, however, in terms of the additional services they are expected to provide, is the introduction of a new discharge medicines service. When NHS patients are discharged from hospital or there is, for other reasons, a transfer of care of them between different providers of NHS services, community pharmacies may be asked to perform a three stage service in respect of the patient, principally linked to changes in medication. The second and third stages of this service are linked to the first prescription presented post-discharge or post-transfer. Issues of concern may be raised by the pharmacy contractor not only with the patient or their carer but also with their general practitioner (regulation 12). Partly to support this new service, pharmacies are required to have a consulting room (previously these were needed to support certain non-mandatory pharmaceutical services), although equivalent remote access arrangements are permitted for distance selling pharmacies and some small pharmacies (regulation 15).

There are also changes to the inspection and access to information requirements to facilitate remote monitoring of pharmacy contractors (regulation 19), and some minor, technical changes. Pharmacy contractors are no longer formally required to undertake training in respect of repeat dispensing (regulation 9(b)), both pharmacy contractors and DACs are required to notify the NHS Commissioning Board if they enter into administration (regulation 3) and there are also changes to the notification requirements when pharmacy contractors and DACs open new premises (regulation 4).