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NHS England

Standard Personal Medical Services Agreement Variation Notice

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Standard Personal Medical Services (PMS) Agreement Variation Notice

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Prepared by Hill Dickinson on behalf of NHS England.

The text of the Standard Personal Medical Services (PMS) Agreement Variation Notice February 2023 has been prepared by Hill Dickinson on behalf of NHS England.

It is prepared on the basis that the signed agreement to be varied is in the form of the NHS England Standard Personal Medical Services Agreement and is up to date with all prior variation notices (up to and including the NHS England Standard Personal Medical Services Agreement Variation Notice November 2022).

Equalities and health inequalities statement

"Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities."

Dear Sir/Madam

Notice of Variation to your Personal Medical Services Agreement dated [ ]

We give you notice under paragraph 52(2) of Schedule 2 to the National Health Service (Personal Medical Services Agreements) Regulations 2015 (S.I. 2015/1879) that the terms of your Personal Medical Services Agreement dated [ ] are varied as set out below with effect from [*insert here date on which variations will take effect. Where reasonably practicable this should not be less than 14 days after the date on which this notice is served. This is a regulatory requirement.*].

These variations are made to comply with the National Health Service (Amendments Relating to Pre-Payment Certificates, Hormone Replacement Therapy Treatments and Medicines Shortages) Regulations 2023, which came into force since the last update to the Standard Personal Medical Services Agreement.

These variations are also made to bring the copy of the terms of service of dispensing doctors included within the Agreement fully up to date with changes to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

For the avoidance of doubt nothing in this notice shall affect accrued rights or liabilities up to the date of the variation.

We request you to acknowledge receipt of this notice by signing and returning the enclosed duplicate of it.

Dated:

Signed:

on behalf of [INSERT ICB NAME]

Print name:

Wording of Variations

Part 1

1. In clause 1.1:

1.1. **Insert** the following definition:

"**"English Health Service Medicine"** means a medicinal product used to any extent for the purposes of the health service continued under section 1(1) of the 2006 Act;";

Schedule 4

2. After paragraph 1.1, **insert** the following:

"**Prescribing software and supply shortages etc. of medicines**

1.1A.1. This paragraph applies where:

1.1A.1.1 the Secretary of State, in the exercise of the Secretary of State's obligations, duties or powers in respect of ensuring that adequate supplies of English Health Service Medicines are available:

1.1A.1.1.1. has acquired information under Part 6 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018 (information about price and availability of health service medicines) about a particular English Health Service Medicine; and

1.1A.1.1.2. authorises the disclosure of information derived from that information ("Relevant Communications Information") to contractors for the purpose of ensuring, by

the appropriate and effective management of:

1.1A.1.1.2.1 a supply shortage of that particular English Health Service Medicine; or

1.1A.1.1.2.2 the discontinuation of the production of that particular English Health Service Medicine;

that adequate supplies of English Health Service Medicines are available;

1.1A.1.2 the Contractor wishes to receive Relevant Communications Information via the prescribing software that it has to support the issuing of prescriptions for English Health Service Medicines (in addition to the other ways in which it may access that information); and

1.1A.1.3 there is a software programme available to the Contractor from its supplier of prescribing software ("SPS") that would enable that.

1.1A.2 Where paragraph 1.1A.1 applies, the Contractor must ensure that the arrangements it makes with a SPS to support the issuing of prescriptions for English Health Service Medicines:

1.1A.2.1 include appropriate provision requiring the updating of the software to take account of Relevant Communications Information about supply shortages of, or the discontinuation of the production of, particular English Health Service Medicines; and

1.1A.2.2 are, as regards that inclusion, consistent with the authorisation referred to in paragraph 1.1A.1.1.2.

1.1A.3 The disclosure of Relevant Communications Information by the Secretary of State or a person acting on the Secretary of State's behalf to a SPS, or by a SPS to a contractor in a manner that is consistent with the authorisation referred to in paragraph 1.1A.1.1.2, is not a disclosure of confidential or commercially sensitive information affected by section 264B(2)(b) of the 2006 Act in a case where but for this paragraph it would be if the disclosure is:

1.1A.3.1 for the purpose of ensuring, by the appropriate and effective management by the Secretary of State (and persons acting on the Secretary of State's behalf) of:

1.1A.3.1.1 a supply shortage of the particular English Health Service Medicine in question; or

1.1A.3.1.2 the discontinuation of the production of the particular English Health Service Medicine in question;

that adequate supplies of English Health Service Medicines are available; and

1.1A.3.2 proportionate to that purpose.

1.1A.4 A disclosure of Relevant Communications Information as mentioned in paragraph 1.1A.3 may be by way of permitting access to that information rather than proactive disclosure.

1.1A.5 A disclosure of Relevant Communications Information that is as mentioned in paragraph 1.1A.3 is to be treated as neither constituting a breach of confidence nor prejudicing commercial interests in any case where, but for this paragraph, it would be so treated.

1.1A.6 Section 264B(3)(f) of the 2006 Act applies to the Contractor in respect of Relevant Communications Information received as part of the arrangements mentioned in paragraph 1.1A.2 as it would if

the Secretary of State had disclosed that information to the Contractor directly instead of via an intermediary.

1.1A.7 A SPS must not disclose Relevant Communications Information, other than as provided for in paragraph 1.1A.3, if it is confidential or commercially sensitive information that, when disclosed to a contractor by the Secretary of State, is subject to the disclosure restriction in section 264B(2)(b) of the 2006 Act.";

3. After paragraph 1.6, **insert** the following:

"1.6A.1 A Prescriber must only order one prescription item on a Prescription Form or Repeatable Prescription that is used by the Prescriber for ordering a Listed HRT Prescription Item.

1.6A.2 For the purposes of paragraph 1.6A.1, "Listed HRT Prescription Item" is to be construed in accordance with regulation 17A(1)(a) of the National Health Service (Charges for Drugs and Appliances) Regulations 2015, read with regulation 17A(7) of those Regulations.".

Schedule 14

4. In paragraph 9(a)(ii), **delete** the final word "or";

5. In paragraph 9(b), after the words "***dispensing doctor*** receives" **insert** the words "as a ***nominated dispensing contractor***";

6. In paragraph 10(a), **delete** the final word "or";

7. After paragraph 14, **insert** the following:

"**Supply in accordance with a Serious Shortage Protocol ("*SSP*")**

14A. This sub-paragraph applies where, in relation to an order for a drug or an ***appliance*** on a ***prescription form*** or a repeatable prescription:

(a) a ***SSP*** has effect in respect of:

(i) the requested drug or ***appliance***; or

(ii) drugs or ***appliances*** of a specified description, and the requested drug or ***appliance*** is of that description.

(b) Where sub-paragraph (a) applies and the ***dispensing doctor*** provides a different product or quantity of product to

the product or quantity of product ordered on the ***prescription form*** or repeatable prescription, in accordance with the ***SSP***:

(i) the ***dispensing doctor*** must endorse the prescription or the associated ***batch issue*** accordingly (if the manner for making the endorsement is provided for in the Drug Tariff, in the manner provided for in the Drug Tariff); and

(ii) the prescription or associated ***batch issue*** as thus endorsed is treated as being the prescription for product reimbursement purposes (even though the supply is not in pursuance of that prescription).

(c) Where the ***dispensing doctor*** provides a drug or ***appliance*** under this paragraph, the ***dispensing doctor*** must include in the dispensing label on the packaging of the product, for the patient's benefit, information to the effect that the product is being supplied in accordance with a ***SSP***, identifying the particular ***SSP***.

Supply in accordance with a Pandemic Treatment Protocol ("*PTP*") or a Pandemic Treatment Patient Group Direction ("*PTPGD*")

14B (a) Subject to the following provisions of this Schedule, where:

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

(ii) a person who is entitled to be supplied with that drug by the ***dispensing doctor*** (Part 8 of the Pharmaceutical Regulations and this Schedule having that effect) in pursuance of that order requests the provision of the drug in accordance with that order;

the ***dispensing doctor*** must, with reasonable promptness, provide the drug so ordered.

(aa) Where the ***dispensing doctor*** considers:

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

(ii) having made the appropriate checks; and

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

that a person is entitled to be supplied with the drug by the ***dispensing doctor*** (Part 8 of the Pharmaceutical Regulations and this Schedule having that effect) in accordance with the ***PTP*** or ***PTPGD*** as part of pharmaceutical services, the ***dispensing doctor*** must, with reasonable promptness,

provide the drug requested.

(b) If a person requesting the provision of the drug asks the ***dispensing doctor*** to do so:

(i) the ***dispensing doctor*** must give an estimate of the time when the drug will be ready; and

(ii) if they are not ready by then, the ***dispensing doctor*** must give a revised estimate of the time when they will be ready (until they are ready).

(c) Where the ***dispensing doctor*** provides a drug under sub-paragraph (a) or (aa), the ***dispensing doctor*** 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*** or a ***PTPGD***, identifying the particular ***PTP*** or ***PTPGD***.

(d) Sub-paragraph (a) 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***.

(e) Sub-paragraph (aa) 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***.

Supply in accordance with a Listed Prescription Items Voucher ("*LPIV*")

14C (a) Subject to the following provisions of this Schedule, where:

(i) the ***dispensing doctor*** receives a ***LPIV***; and

(ii) a person who is entitled to be supplied by the ***dispensing doctor*** (Part 8 of the Pharmaceutical Regulations 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***, the ***dispensing doctor*** must, with reasonable promptness, provide the prescription item so ordered.

(b) If a person who is entitled as mentioned in sub-paragraph (a)(ii) asks the ***dispensing doctor*** to do so:

(i) the ***dispensing doctor*** must give an estimate of the time when the prescription item will be ready; and

(ii) if they are not ready by then, the ***dispensing doctor*** must give a revised estimate of the time when the item will be ready (until it is ready).

(c) Sub-paragraph (a) 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***.";

8. In paragraph 15, after the words "with paragraph 14" **insert** the words "or 14A";

9. In paragraph 15, **replace** the words "of regulation 10(1)" with the words "of regulation 10";

10. In paragraphs 15 and 16, **replace** sub-paragraph 15(d) and paragraph 16 with the following:

"(d) in the case of an ***electronic prescription***, the ***dispensing doctor*** must ensure that the following information is duly entered into the records managed by NHS England that are accessible as part of the Electronic Prescription Service (if either it is not already recorded in those records or a check, known as a real time exemption check, has not produced satisfactory evidence as mentioned in sub-paragraph (a)):

(i) in a case where the exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of:

(aa) the exemption category specified in regulation 10(1) of the ***Charges Regulations*** or the ground for remission under regulation 5 of the ***Remission of Charges Regulations*** which it is claimed applies to the case; and

(bb) whether or not satisfactory evidence was produced to the ***dispensing doctor*** as required by sub-paragraph 15(a);

(ii) in any case where a charge is due, confirmation that the relevant charge was paid; and

(iii) in the case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

16. Not used."

11. In paragraph 16A, **replace** the words "paragraphs 15 and 16" with the words "paragraph 15";

12. After paragraph 16B, **insert** the following:

"Checks and records in the case of supply in accordance with a *SSP*

16C. In a case involving providing drugs or ***appliances*** in accordance with paragraph 14A, the references in paragraph 15 to a ***prescription form*** or ***repeatable prescription*** are to be construed as references to the prescription for product reimbursement purposes, as mentioned in paragraph 14A(b)(ii).";

13. In paragraph 21(a), after the words "a genuine order" **insert** the words "or valid request";

14. After paragraph 24, **insert** the following:

"24A. The ***dispensing doctor*** must refuse to provide a drug or ***appliance*** ordered on a ***prescription form*** or a ***repeatable prescription*** where:

(a) a ***SSP*** has effect in respect of:

(i) the requested drug or ***appliance***; or

(ii) drugs or ***appliances*** of a specified description, and the requested drug or ***appliance*** is of that description; and

(b) alternative provision has already taken place in accordance with the ***SSP***.

24B. The ***dispensing doctor*** may refuse to fulfil an order or a request for a drug that is or is purportedly in accordance with a ***LPIV***, a ***PTP*** or a ***PTPGD*** where:

(a) The ***dispensing doctor*** 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 the ***dispensing doctor*'s** clinical judgement;

(c) the ***dispensing doctor*** 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.

24C. The ***dispensing doctor*** must refuse to provide, pursuant to a ***LPIV***, a ***PTP*** or a ***PTPGD***, an order or a request for a drug that is or is purportedly in accordance with the ***LPIV***, the ***PTP*** or ***PTPGD*** where the ***dispensing doctor*** is not satisfied that it is in accordance with the ***LPIV***, the ***PTP*** or ***PTPGD***.

24D. The ***dispensing doctor*** may refuse to provide a prescription item ordered on a ***prescription form*** or ***repeatable prescription*** where:

(a) more than one prescription item has been ordered on the ***prescription form*** or ***repeatable prescription***;

(b) at least one of those prescription items is a ***listed HRT prescription item*** and at least one of those prescription items is not; and

(c) the person named on the ***prescription form*** or ***repeatable prescription*** is claiming entitlement to exemption under regulation 10(1)(j) of the Charges Regulations (exemptions) in respect of any of those prescription items which is a ***listed HRT prescription item***.

For the purposes of this paragraph, "listed HRT prescription item" is to be construed in accordance with regulation 17A(1)(a) of the National Health Service (Charges for Drugs and Appliances) Regulations 2015, read with regulation 17A(7) of those Regulations.";

15. After paragraph 25, **insert** the following:

"Home delivery service while a disease is or in anticipation of a disease being imminently pandemic etc.

25A. (a) Before dispensing any item on a ***prescription form*** or supplying it in accordance with a ***SSP***, the ***dispensing doctor*** must provide a home delivery option to eligible patients in respect of the item where, as a consequence of a disease being or in anticipation of a disease being imminently:

(i) pandemic; and

(ii) a serious risk or potentially a serious risk to human health;

NHS England with the agreement of the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, eligible patients are advised to stay away from listed dispensing premises in the area specified, in the circumstances specified and for the duration of the period specified in the announcement.

(b) If the ***dispensing doctor's*** listed dispensing premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from the ***dispensing doctor's*** premises, the ***dispensing doctor*** must ascertain from:

(i) an eligible patient:

(aa) who has contacted the ***dispensing doctor*** about the home delivery of prescription items; or

(bb) who is a person whom the ***dispensing doctor*** considered, on the basis of the nature of an item on a ***prescription form***, might be an eligible

person and accordingly, in the ordinary exercise of professional skill and judgement, made the appropriate checks and determined that they were; or

(ii) a person who may make an application for pharmaceutical services on behalf of that eligible patient (a "duly authorised person") who has contacted the ***dispensing doctor*** about the home delivery of prescription items;

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

(c) Where paragraph (b) does not apply, if the ***dispensing doctor's*** listed dispensing premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from ***dispensing doctor's*** premises, the home delivery option that P must provide must comprise:

(i) the ***dispensing doctor*** delivering the item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);

(ii) the ***dispensing doctor*** arranging for an item dispensed by the ***dispensing doctor*** to be delivered by another ***dispensing doctor***, or by an ***NHS pharmacist*** or an ***LPS contractor***, to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person; or

(iii) if the ***dispensing doctor*** is unable to deliver the item or arrange for its delivery by another ***dispensing doctor***, or by an ***NHS pharmacist*** or by an ***LPS contractor***, the ***dispensing doctor*** arranging for the dispensing or supply of the item by another ***dispensing doctor***, or by an ***NHS pharmacist*** or an ***LPS contractor***, who would be able to deliver the dispensed item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person.

(d) Paragraph (a) does not apply where the eligible patient or a duly authorised person is already at the ***dispensing doctor's*** listed dispensing premises for the purposes of receiving dispensing services.

(e) Notwithstanding the foregoing provisions of this Schedule, in any case of a supply in accordance with a home delivery option, if but for this sub-paragraph that supply would need to be made with reasonable promptness, the ***dispensing doctor*** may

instead, in the exercise of professional skill and judgment, make the supply within a reasonable timescale.

(f) For the purposes of paragraphs 25A and 25AA, an "LPS contractor" means a person who is an ***LPS chemist*** by virtue of being a party to an ***LPS scheme*** which is not an ***LPS pilot scheme***.

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

25AA (a) Before dispensing a notified item on a ***prescription form*** or supplying it in accordance with an ***SSP***, a ***PTP*** or a ***PTPGD***, the ***dispensing doctor*** must provide a home delivery option to eligible patients in respect of that item.

(b) For the purposes of this paragraph, a "notified item" is an item that, as a consequence of a disease being or in anticipation of a disease being imminently:

(i) pandemic; and

(ii) a serious risk or potentially a serious risk to human health,

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

(c) Where the ***dispensing doctor*** is to, or may be required to, dispense a notified item on a ***prescription form*** or supply it in accordance with an ***SSP***, a ***PTP*** or a ***PTPGD***, the ***dispensing doctor*** must ascertain from:

(i) an eligible patient:

(aa) who has contacted the ***dispensing doctor*** about the home delivery of a notified item, or

(bb) who is a person whom the ***dispensing doctor*** considered, on the basis of an order or request for a notifiable item, might be an eligible person and accordingly, in the ordinary exercise of professional skill and judgement, made the appropriate checks and determined that they were; or

(ii) a person who may make an application for pharmaceutical services on behalf of that eligible patient

(a "duly authorised person") who has contacted the ***dispensing doctor*** about the home delivery of a notified item, whether or not the item could be supplied via a duly authorised person, and if it could, then supplying the item via a duly authorised person is the home delivery option which the ***dispensing doctor*** must provide.

(d) Where paragraph (c) does not apply, the home delivery option that the ***dispensing doctor*** must provide must comprise:

(i) the ***dispensing doctor*** delivering the item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);

(ii) the ***dispensing doctor*** arranging for an item dispensed by the ***dispensing doctor*** to be delivered by another ***dispensing doctor***, or by an ***NHS pharmacist*** or an ***LPS contractor***, to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person; or

(iii) if the ***dispensing doctor*** is unable to deliver the item or arrange for its delivery by another dispensing doctor, or by an ***NHS pharmacist*** or an ***LPS contractor***, the ***dispensing doctor*** arranging for the dispensing or supply of the item by another ***dispensing doctor***, or by an ***NHS pharmacist*** or an ***LPS contractor***, who would be able to deliver the item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person.

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

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

I/We [ ] acknowledge receipt of the notice of variation dated [ ] of which the above is a duplicate. I/We acknowledge that this notice will take effect from [ ].

Signed:

[on behalf of]:

Print name:

Date: