STATUTORY INSTRUMENTS

2023 No. 171

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Amendments Relating to Pre-Payment Certificates, Hormone Replacement Therapy Treatments and Medicines Shortages) Regulations 2023

Made - - - -	*20th February 2023*
Laid before Parliament	*21st February 2023*
Coming into force	*1st April 2023*

CONTENTS

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 89(1) and (2)(a) and (d), 94(1) and (3)(d) and (f), 126, 129, 132(1), 172(1), 174, 178(1)(b), (2)(a) and (b) and (3), 182 and 272(7) and (8)(a) of, and paragraph 3(1) and (3)(c) and (f) of Schedule 12 to, the National Health Service Act 2006(**a**).

(**a**) 2006 c. 41. Section 126 of the National Health Service Act 2006 ("the 2006 Act") 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; the Children and Social Work Act 2017 (c. 16), Schedule 5, paragraphs 30 and 47(j); and the Health and Care Act 2022 (c. 31) ("the 2022 Act"), Schedule 1, paragraph 1. Section 129 of the 2006 Act has been amended by: the Health Act 2009 (c. 21), 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; the 2022 Act, Schedule 1, paragraph 1; and S.I. 2010/231. *See* section 275(1) of the 2006 Act for the definitions of "prescribed" and "regulations" that are relevant to the powers being

Citation, commencement, extent, application and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Amendments Relating to Pre-Payment Certificates, Hormone Replacement Therapy Treatments and Medicines Shortages) Regulations 2023 and come into force on 1st April 2023.

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

(3) In these Regulations—

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

Amendment of regulation 2 of the PLPS Regulations

2. In regulation 2 of the PLPS Regulations(**e**) (interpretation), in paragraph (1), at the appropriate place in the alphabetical order insert—

> ""listed HRT prescription item" is to be construed in accordance with regulation 17A(1)(a) of the Charges Regulations (HRT only pre-payment certificates), read with regulation 17A(7) of those Regulations;".

Amendment of Schedule 4 to the PLPS Regulations

3. In Schedule 4 to the PLPS Regulations (terms of service of NHS pharmacists), in paragraph 9(**f**) (refusal to provide drugs or appliances ordered), after sub-paragraph (6) insert—

> "(7) P 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.".

Amendment of Schedule 6 to the PLPS Regulations

4. In Schedule 6 to the PLPS Regulations (terms of service of dispensing doctors), in paragraph 6(**g**) (refusal to provide drugs or appliances ordered), after sub-paragraph (6) insert—

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exercised. The powers conferred by these sections are exercisable by the Secretary of State only in relation to England, by virtue of section 271(1) of the 2006 Act.

(**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, 2020/1126, 2021/169 and 1346 and 2022/634 and 930.
(**f**) Amended by S.I. 2018/1114, 2019/990, 2020/1126 and 2021/169 and 1347.
(**g**) Amended by S.I. 2018/1114, 2019/990, 2020/1126 and 2021/169 and 1347.

"(7) D 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.".

Amendment of Schedule 7 to the PLPS Regulations

5. In Schedule 7 to the PLPS Regulations (mandatory terms for LPS schemes), in paragraph 7(**a**) (refusal to provide drugs or appliances ordered), after sub-paragraph (6) insert—

"(7) C 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.".

Amendment of regulation 2 of the Charges Regulations

6. In regulation 2 of the Charges Regulations(**b**) (interpretation), at the appropriate places in the alphabetical order insert—

""listed HRT prescription item" is to be construed in accordance with regulation 17A(1)(a), read with regulation 17A(7);"; and

""HRT only PPC" has the meaning given in regulation 17A(1)(a);".

Amendment of regulation 10 of the Charges Regulations

7. In regulation 10 of the Charges Regulations (exemptions: general), in paragraph (1)—

(a) omit "or" at the end of sub-paragraph (h);

(b) add "; or" at the end of sub-paragraph (i); and

(c) after sub-paragraph (i) insert—

"(j) has a valid HRT only PPC, but only in respect of a prescription item that is a listed HRT prescription item.".

Substitution of regulation 13A of the Charges Regulations

8. For regulation 13A of the Charges Regulations(**c**) (exemption from charges: supply of a smaller quantity of a product in accordance with a SSP) substitute—

(**a**) Amended by S.I. 2018/1114, 2019/990, 2020/1126 and 2021/169 and 1347.
(**b**) Amended by S.I. 2015/1879, 2016/696 and 1077, 2018/1114, 2019/248, 990 and 1094, 2021/169 and 1346 and 2022/169 and 1346.
(**c**) Inserted by S.I. 2019/990.

"**Exemption from charges: supplies in accordance with a SSP**

13A.—(1) No charge is payable under regulation 3(1) or (2) or 4(1) in respect of the supply of a drug or appliance in accordance with a SSP if, as a consequence of the supply being in accordance with a SSP instead of being in accordance with a prescription form or an associated batch issue, the patient receives a smaller quantity of the drug or fewer appliances than the quantity originally ordered.

(2) If, as a consequence of the supply of a drug or appliance being in accordance with a SSP instead of being in accordance with a prescription form or an associated batch issue—

(a) more than one charge would (but for this sub-paragraph) become payable under regulation 3(1) or (2) or 4(1) in respect of what is supplied in accordance with the SSP instead of only one charge being payable, then only one charge is payable in respect of what is supplied in accordance with that SSP; or

(b) a charge would (but for this sub-paragraph) become payable under regulation 3(1) or (2) or 4(1) in respect of what is supplied in accordance with the SSP instead of no charge being payable, then no charge is payable in respect of what is supplied in accordance with that SSP.".

Amendment of regulation 17 of the Charges Regulations

9. In regulation 17 of the Charges Regulations(**a**) (pre-payment certificates: repayment), after paragraph (10) insert—

"(11) This regulation does not apply to a HRT only PPC.".

New regulation 17A of the Charges Regulations

10. After regulation 17 of the Charges Regulations (pre-payment certificates: repayment) insert—

"HRT only pre-payment certificates

17A.—(1) The Secretary of State may make arrangements for the grant of pre-payment certificates solely in respect of prescription items that are used for hormone replacement therapy (HRT) treatment, in particular by—

(a) publishing in the Drug Tariff a list of the drugs and appliances ("listed HRT prescription items") in respect of which no charge is payable by a person on whom exemption from charging in respect of the listed HRT prescription items is conferred by the granting of such a certificate (referred to in these Regulations as a "HRT only PPC"); and

(b) specifying how applications for the grant of HRT only PPCs are to be made.

(2) Any such arrangements must provide that a patient may apply for a HRT only PPC whether or not the listed HRT prescription items are prescribed for them for use for HRT treatment or for some other purpose.

(3) The list mentioned in paragraph (1)(a) is only to include those of the prescription items used for HRT treatment that the Secretary of State wishes to include in the arrangements mentioned in paragraph (1), not all the prescription items that may be used for HRT treatment.

(4) In order to benefit from any arrangements as mentioned in paragraph (1), a patient or someone acting on their behalf (an "applicant") may apply for a HRT only PPC, but if an applicant does so, the applicant must—

(**a**) There are no relevant amending instruments.

(a) pay to the Secretary of State the sum payable for the HRT only PPC, which is £18.70 (and an application is not valid if that amount has not been received by the Secretary of State); and

(b) provide the Secretary of State with the information required to determine that application by—

(i) duly completing and submitting an application for a HRT only PPC on a form approved by the Secretary of State and provided for that purpose, or

(ii) providing the Secretary of State with that information in a manner that is otherwise acceptable to the Secretary of State.

(5) A HRT only PPC is valid for a period of 12 months and an application for a HRT only PPC must include the date from which the patient wishes it to be valid.

(6) A HRT only PPC is valid from the date included in the application pursuant to paragraph (5), where the applicant has specified a date that is—

(a) before the application is made and that date is no more than one month prior to the date on which the application is made (so if the application is made on 1st May, the start date may be no earlier than 1st April);

(b) the date on which the application is made; or

(c) after the application is made and that date is no more than one month after the date on which the application is made (so if the application is made on 1st April, the start date may be no later than 1st May),

but otherwise, the HRT only PPC is valid from the date on which the application is received.

(7) A HRT only PPC is only valid in respect of a prescription item that is a listed HRT prescription item at the time of the supply of the prescription item, unless—

(a) the prescription item was a listed HRT prescription item before that time but it has since been removed from the list in the Drug Tariff; and

(b) it was a listed HRT prescription item at the time the prescription in pursuance of which the product is supplied was issued (whether the product is supplied in accordance with that prescription or a serious shortage protocol),

in which case, the HRT only PPC is also valid in respect of that product.

(8) As regards any HRT only PPCs that are to be valid during the first month for which any arrangements as mentioned in paragraph (1) are made—

(a) the date to be included by the applicant in the application pursuant to paragraph (5) must be a date no earlier than the date on which the arrangements start; and

(b) if an earlier start date for the HRT only PPC is included but the application is otherwise valid, the HRT only PPC is valid from the date on which the arrangements start.".

Amendment of regulation 3 of the GMS Regulations

11. In regulation 3 of the GMS Regulations(**a**) (interpretation), in paragraph (1), at the appropriate place in the alphabetical order insert—

""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 Act;".

(**a**) Amended by S.I. 2016/696 and 1077, 2018/844 and 1114, 2019/593, 1094 and 1137, 2020/226 and 351, 2021/331, 995 and 1346 and 2022/634 and 935.

New regulation 55A of the GMS Regulations

12. After regulation 55 of the GMS Regulations(**a**) (prescribing: general), insert—

"Prescribing software and supply shortages etc. of medicines

55A.—(1) This paragraph applies where—

(a) 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—

(i) has acquired information under Part 6 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018(**b**) (information about price and availability of health service medicines) about a particular English health service medicine, and

(ii) 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—

(aa) a supply shortage of that particular English health service medicine, or

(bb) the discontinuation of the production of that particular English health service medicine,

that adequate supplies of English health service medicines are available;

(b) 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

(c) there is a software programme available to the contractor from its supplier of prescribing software ("SPS") that would enable that.

(2) Where paragraph (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—

(a) 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

(b) are, as regards that inclusion, consistent with the authorisation referred to in paragraph (1)(a)(ii).

(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)(a)(ii), is not a disclosure of confidential or commercially sensitive information affected by section 264B(2)(b) of the Act, in a case where but for this paragraph it would be, if the disclosure is—

(a) 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—

(i) a supply shortage of the particular English health service medicine in question, or

(ii) 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

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(**a**) Amended by S.I. 2019/1137.
(**b**) S.I. 2018/677.

(b) proportionate to that purpose.

(4) A disclosure of relevant communications information as mentioned in paragraph (3) may be by way of permitting access to that information rather than proactive disclosure.

(5) A disclosure of relevant communications information that is as mentioned in paragraph (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.

(6) Section 264B(3)(f) of the Act applies to the contractor in respect of relevant communications information received as part of the arrangements mentioned in paragraph (2) as it would if the Secretary of State had disclosed that information to the contractor directly instead of via an intermediary.

(7) A SPS must not disclose relevant communications information, other than as provided for in paragraph (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 Act.".

Amendment of regulation 56 of the GMS Regulations

13. In regulation 56 of the GMS Regulations(**a**) (orders for drugs, medicines or appliances), after paragraph (5) insert—

"(5A) 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.

(5B) For the purposes of paragraph (5A), "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.".

Amendment of regulation 3 of the PMS Regulations

14. In regulation 3 of the PMS Regulations(**b**) (interpretation), in paragraph (1), at the appropriate place in the alphabetical order insert—

""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 Act;".

New regulation 48A of the PMS Regulations

15. After regulation 48 of the PMS Regulations(**c**) (prescribing: general), insert—

"Prescribing software and supply shortages etc. of medicines

48A.—(1) This paragraph applies where—

(a) 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—

(i) has acquired information under Part 6 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018(**d**) (information about price and availability of health service medicines) about a particular English health service medicine, and

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(**a**) Amended by S.I. 2018/1114.
(**b**) Amended by S.I. 2016/696 and 1077, 2018/844 and 1114, 2019/593, 1094 and 1137, 2020/226 and 351, 2021/331, 995 and 1346 and 2022/634 and 935.
(**c**) Amended by S.I. 2019/1137.
(**d**) S.I. 2018/677.

(ii) 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—

(aa) a supply shortage of that particular English health service medicine, or

(bb) the discontinuation of the production of that particular English health service medicine,

that adequate supplies of English health service medicines are available;

(b) 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

(c) there is a software programme available to the contractor from its supplier of prescribing software ("SPS") that would enable that.

(2) Where paragraph (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—

(a) 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

(b) are, as regards that inclusion, consistent with the authorisation referred to in paragraph (1)(a)(ii).

(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)(a)(ii), is not a disclosure of confidential or commercially sensitive information affected by section 264B(2)(b) of the Act, in a case where but for this paragraph it would be, if the disclosure is—

(a) 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—

(i) a supply shortage of the particular English health service medicine in question, or

(ii) 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

(b) proportionate to that purpose.

(4) A disclosure of relevant communications information as mentioned in paragraph (3) may be by way of permitting access to that information rather than proactive disclosure.

(5) A disclosure of relevant communications information that is as mentioned in paragraph (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.

(6) Section 264B(3)(f) of the Act applies to the contractor in respect of relevant communications information received as part of the arrangements mentioned in paragraph (2) as it would if the Secretary of State had disclosed that information to the contractor directly instead of via an intermediary.

(7) A SPS must not disclose relevant communications information, other than as provided for in paragraph (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 Act.".

Amendment of regulation 49 of the PMS Regulations

16. In regulation 49 of the PMS Regulations(**a**) (orders for drugs, medicines or appliances), after paragraph (5) insert—

"(5A) 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.

(5B) For the purposes of paragraph (5A), "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.".

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

Neil O'Brien
Parliamentary Under Secretary of State,
Department of Health and Social Care

20th February 2023

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"), which 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 or a personal medical services agreement made pursuant to Part 4 of the 2006 Act.

The amendments made to the Charges Regulations provide for the introduction of a pre-payment certificate (PPC) purchasable by NHS patients who are prescribed hormone replacement therapy (HRT) drugs or appliances which are on a list of HRT products that is to be published in the Drug Tariff ("the Drug Tariff list"). Purchasers of such PPCs will be exempt from any prescription charges that would otherwise be payable for the products on the Drug Tariff list under the Charges Regulations. These PPCs will be valid for a period of 12 months (regulations 6, 7, 9 and 10).

If a HRT product is on the Drug Tariff list, prescribers in GP practices that hold contracts under the GMS Regulations or the PMS Regulations are required to prescribe one item per NHS prescription form or repeatable prescription, whenever they prescribe items on that list (the number of items that they may prescribe on each NHS prescription form or repeatable prescription is not otherwise restricted under the GMS Regulations or the PMS Regulations) (regulations 13 and 16). If a NHS community pharmacy or the dispensary of a NHS dispensing doctor does receive a NHS prescription form or repeatable prescription with at least one item on the Drug Tariff list on it, together with at least one other item, they may refuse to dispense any of the items on that prescription form or repeatable prescription if the patient is claiming a prescription charge exemption for any of those items on the basis of the new PPC (regulations 2 to 5).

Ordinarily, community pharmacies must dispense exactly what is written on a prescription form or repeatable prescription but in the event of actual or anticipated serious shortages, the Secretary of State has the power to issue Serious Shortage Protocols (SSPs) to enable them to dispense alternatives. If a smaller quantity of a drug or appliances needs to be dispensed, patients who

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

would otherwise have needed to pay a prescription charge were already exempt from doing so. This principle is extended so that if additional items have to be dispensed (for example, a new inhaler to support the supply of an alternative drug), no additional prescription charges are payable (regulation 8).

Where the Secretary of State acquires information about medicines shortages or the discontinuation of the supply of medicines under the Health Service Products (Provision and Disclosure of Information) Regulations 2018 (S.I. 2018/677), he or she has powers to pass that information on to providers of NHS services such as GP practices. However, prior to these Regulations, no statutory gateway existed for the Secretary of State to supply that information to GP practices via intermediaries who would not otherwise be authorised to have that information, such as providers of GP prescribing software. Where a GP practice that holds a contract under the GMS or PMS Regulations wishes to receive this type of information via their prescribing software and the supplier of the prescribing software is able to fulfil that wish, a new obligation is imposed on the GP practice, as part of their GP contract, to include in their contract with their supplier of prescribing software appropriate provision to reflect that wish – giving effect to which is then supported by the creation of the necessary statutory gateway (regulations 11, 12, 14 and 15).

An impact assessment in relation to the measures in these Regulations that relate to prepayment certificates for hormone replacement therapy treatments is available from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU. A copy of it is also published alongside this instrument on www.legislation.gov.uk. A full impact assessment has not been undertaken in relation to the other measures in these Regulations as they are not expected to have a significant impact on the public and voluntary sectors, and only a limited impact on the private sector, below the threshold for undertaking a full impact assessment.

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