This Statutory Instrument has been made in part as a consequence of a defect in S.I. 2023/171 and is being issued free of charge to all known recipients of that Statutory Instrument.

STATUTORY INSTRUMENTS

2023 No. 300

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2023

Made - - - - March 2023

Laid before Parliament March 2023

Coming into force - - - 1st April 2023

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 172, 174, 178, 182 and 272(7) and (8) of the National Health Service Act 2006(1).

Citation, commencement, interpretation, extent and application

- 1.—(1) These Regulations may be cited as the National Health Service (Charges for Drugs and Appliances) (Amendment) Regulations 2023 and come into force on 1st April 2023.
- (2) In these Regulations, "the Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2015(2).
 - (3) These Regulations extend to England and Wales, and apply only to England(3).

Amendment of the Charges Regulations

2. The Charges Regulations are amended in accordance with regulations 3 to 6.

Amendments relating to charges for drugs and appliances

3.—(1) In each of the following provisions, for "£9.35", substitute "£9.65"—

^{(1) 2006} c. 41. See section 275(1) of the National Health Service Act 2006 ("the Act") for the definitions of "prescribed" and "regulations" that are relevant to the powers being exercised.

⁽²⁾ S.I. 2015/570; as amended by S.I. 2015/1879, 2016/325, 696 and 1077, 2017/408, 2018/48 (W.15), 201 and 1114, 2019/248, 287, 990 and 1094, 2020/201, 885 and 1126, 2021/169, 178 and 1346, 2022/634 and 2023/98 and 171.

⁽³⁾ By virtue of section 271(1) of the Act, the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England.

- (a) regulation 3(1)(a), (b) and (c), (2)(a), (b) and (c) and (7) (supply of drugs and appliances by chemists);
- (b) regulation 4(1)(a), (b) and (c) and (4) (supply of drugs and appliances by doctors);
- (c) regulation 5(1)(a), (b) and (c) (out of hours supply of drugs and appliances by providers of out of hours services);
- (d) regulation 6(1)(a), (d) and (e) (supply of drugs and appliances by NHS trusts and NHS foundation trusts);
- (e) regulation 7(1)(a), (b) and (c) and (5) (supply of drugs and appliances at walk-in centres);
- (f) regulation 8(1) (supply of drugs under Patient Group Directions); and
- (g) regulation 9(1)(a), (d) and (e) and (8) (supply of drugs and appliances by other providers of NHS services).
- (2) In each of the following provisions, for "£18.70", substitute "£19.30"—
 - (a) regulation 3(1)(a) and (2)(a) (supply of drugs and appliances by chemists);
 - (b) regulation 4(1)(a) (supply of drugs and appliances by doctors);
 - (c) regulation 5(1)(a) (out of hours supply of drugs and appliances by providers of out of hours services);
 - (d) regulation 6(1)(a) and (c) (supply of drugs and appliances by NHS trusts and NHS foundation trusts);
 - (e) regulation 7(1)(a) (supply of drugs and appliances at walk-in centres); and
 - (f) regulation 9(1)(a) and (b) (supply of drugs and appliances by other providers of NHS services).
- (3) In column (2) of Schedule 1 (charges for fabric supports and wigs)—
 - (a) for "£30.70" substitute "£31.70";
 - (b) for "£46.30" substitute "£47.80";
 - (c) for "£75.70" substitute "£78.15";
 - (d) for "£200.50" substitute "£207.00"; and
 - (e) for "£293.20" substitute "£302.70".

Amendment of regulation 16

- **4.** In regulation 16(3) (pre-payment certificates: application and grant)—
 - (a) in sub-paragraph (a), for "£30.25" substitute "£31.25";
 - (b) in sub-paragraph (b), for "£108.10" substitute "£111.60"; and
 - (c) in sub-paragraph (c), for "£10.81" substitute "£11.16".

Amendment of regulation 17

- **5.** In regulation 17 (pre-payment certificates: repayment)—
 - (a) in paragraph (4)—
 - (i) in sub-paragraph (a), for "£30.25" substitute "£31.25", and
 - (ii) in sub-paragraphs (b) and (c)(i) and (ii), for "£108.10", at each place that it occurs, substitute "£111.60"; and
 - (b) in paragraph (5), for "£30.25" substitute "£31.25".

Substitution of regulation 17A

6. For regulation 17A (HRT only pre-payment certificates)(4) substitute—

"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) pay to the Secretary of State the sum payable for the HRT only PPC, which is £19.30 (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.".

Transitional provision relating to the Charges Regulations

7. Where, on or after 1st April 2023, an appliance specified in Schedule 1 to the Charges Regulations (charges for fabric supports and wigs) is supplied pursuant to an order given before that date, the Charges Regulations are to have effect in relation to that supply as if these Regulations had not come into force.

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

At 12.49 p.m. on 9th March 2023

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Charges for Drugs and Appliances) Regulations 2015 ("the Charges Regulations").

The Charges Regulations include the charges that are payable for the supply of NHS drugs and appliances in England. Regulation 3 amends regulations 3 to 9 of the Charges Regulations to increase the single prescription charge applied for the supply of drugs, appliances and elastic hosiery from £9.35 to £9.65 (if the hosiery charge is for a pair, the charge is double that amount). This is an increase of around 3.21%. There are also increases to the charges for wigs and fabric supports of around 3.24%.

Regulation 4 amends regulation 16 of the Charges Regulations to increase the cost of a 3 month prepayment certificate from £30.25 to £31.25, and the cost of a 12 month pre-payment certificate from £108.10 to £111.60. This increases the monthly cost of paying for a pre-payment certificate by direct debit from £10.81 to £11.16. This is an increase of around 3.24%. Regulation 5 amends regulation 17 of the Charges Regulations to reflect this increase in the costs of pre-payment certificates, which is also to apply in respect of the refunding arrangements that apply in the circumstances specified in that regulation.

Regulation 6 substitutes regulation 17A of the Charges Regulations, with only one amendment. The amendment to it is to increase the cost of the HRT only pre-payment certificate from £18.70 to £19.30. This is an increase of around 3.21%. Regulation 17A was originally inserted into the Charges Regulations by the National Health Service (Amendments Relating to Pre-Payment Certificates, Hormone Replacement Therapy Treatments and Medicines Shortages) Regulations 2023 (S.I. 2023/171). The preamble to those Regulations should have cited section 272(8)(b) of the National Health Service Act 2006, which was relevant to the insertion of regulation 17A. The substitution of the whole of regulation 17A (rather than just of the amount specified in regulation 17A(4)(a)), in reliance on all the necessary powers for the making of it, is to remove any doubt as to the validity of the sub-delegation in regulation 17A arising out of the earlier failure to cite section 272(8)(b).

Regulation 7 makes transitional provision in relation to fabric supports and wigs supplied pursuant to NHS prescriptions written before 1st April 2023.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sectors is foreseen, and only a limited impact on the public sector, below the threshold for producing a full impact assessment.