STATUTORY INSTRUMENTS

2023 No. 171

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

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) 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.".