

Statutory Document No. 22/04

THE NATIONAL HEALTH SERVICE ACT 2001

THE NATIONAL HEALTH SERVICE (CHARGES FOR DRUGS AND APPLIANCES) REGULATIONS 2004

Approved by Tynwald

16th November 2004

Coming into operation

1st December 2004

In exercise of the powers conferred on the Department of Health and Social Security by section 35(1) of the National Health Service Act 2001¹, and of all other enabling powers, and after consultations required by section 42(5) of that Act, the following Regulations are hereby made:—

1. Citation, commencement and interpretation

- (1) These Regulations may be cited as the National Health Service (Charges for Drugs and Appliances) Regulations 2004, and, subject to section 42(1) of the Act, shall come into operation on the 1st December 2004.
 - (2) In these Regulations —

"the Act" means the National Health Service Act 2001;

"appliance" means an appliance which is a prescribed appliance within the meaning of section 8(1) of the Act but does not include a contraceptive appliance;

"contractor" means a person who has undertaken to provide general pharmaceutical services and whose name is included in the pharmaceutical list maintained under section 8 of the Act;

"drugs" includes medicines, but does not include contraceptive substances;

"the Drug Tariff" means a statement published by the Department pursuant to regulation 8 of the National Health Service (General Pharmaceutical Services) Regulations 2004²;

"elastic hosiery" means an anklet, legging, knee-cap, below-knee or thigh stocking;

"exemption" means any remission granted under these regulations from charges payable under these regulations;

^{1 2001} c.14

² SD 20/04

"independent nurse prescriber" means a person —

- (a) who is registered in Sub-Part 1 of the Nurses' Part or in the Midwives' part of the nurses and midwives' professional register; and
- (b) in respect of whom an annotation signifying that he is qualified to order drugs, medicines and appliances from -
 - (i) the Nurse Prescribers' Formulary for Community Nurses and Health Visitors in Part 8B of the Drug Tariff; or
 - (ii) the Nurse Prescribers' Extended Formulary in Part 8C of the Drug Tariff,

is also recorded in that register;

"nursing and midwives professional register" means the register maintained by the Nursing and Midwifery Council pursuant to Article 5 of the Nursing and Midwifery Order 2002³; and

"patient" means —

- (a) a registered patient,
- (b) a temporary resident,
- (c) persons to whom the contractor is required to provide immediately necessary treatment,
- (d) any other person to whom the contractor has agreed to provide services under their General Medical Services contract,
- (e) any person who applies to a pharmacist for the provision of pharmaceutical services;

and includes for the purposes of these Regulations a person acting on behalf of such a person;

"pre-payment certificate" has the meaning given by regulation 5(1);

"prescriber" means a doctor, an independent nurse prescriber or a supplementary prescriber;

"prescription form" means a form provided by the Department and issued by a prescriber or a dentist to enable a person to obtain pharmaceutical services, and includes a prescription form provided and issued under equivalent arrangements having effect in England and Wales, Scotland or Northern Ireland:

"prisoner" means a person who is detained in a prison in which medical, dental, ophthalmic, pharmaceutical and nursing services are provided under the Act by arrangements made by the Department;

"repeatable prescription" means a prescription contained in a form provided by the Department and issued by a repeatable prescriber to enable a person to obtain pharmaceutical services and which —

(a) is generated by a computer but signed by a repeatable prescriber; and

³ SI 2002/253

(b) indicated that the drugs or appliances ordered on that form may be provided more than once, and specifies the number of occasions on which they may be provided;

"supplementary prescriber" means a person

- (a) whose name is registered in
 - (i) Sub-Part 1 of the Nurses' Part, or in the Midwives' Part, of the nurses and midwives' professional register;
 - (ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954 (an Act of Parliament)⁴; or
 - (iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976⁵, and
- (b) whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs and appliances as a supplementary prescriber;

"terms of service" means the terms on which general pharmaceutical services, general dental services or general ophthalmic services are provided under the Act;

"treatment" includes examination and diagnosis.

- (3) For the purposes of these Regulations the supply against an order on one prescription form
 - (a) of quantities of the same drug in more than one container shall be treated as the supply of only one quantity of a drug;
 - (b) of more than one appliance of the same type, except in the case of elastic hosiery and tights, or of two or more component parts of the same appliance, shall be treated as the supply of only one appliance.
- (4) Until the 1st January 2005 the definition of "doctor" in subsection (2) shall have effect with the omission of the words "who holds a licence to practice".

2 Supply of drugs and appliances by contractors

- (1) A contractor who provides pharmaceutical services to a patient shall, subject to paragraph (3), make and recover from that patient
 - (a) in respect of an appliance specified in column 1 of the Schedule, the sum specified in column 2 of the Schedule in respect of that appliance;
 - (b) in respect of the supply of any quantity of a drug, a charge of £3.00.
- (2) Where a charge is paid under paragraph (1), the person making the payment shall on doing so sign a declaration in writing on the prescription form that the relevant charge has been paid.

⁴ 1954 c.51

⁵ SI 1976/1213

- (3) No charge shall be made or recovered under paragraph (1) where —
- (a) there is exemption under regulation 4 and a declaration of entitlement to exemption on the prescription form is duly completed by or on behalf of the patient;
- (b) the patient is resident in a school or institution the name of which is inserted on the prescription form by a prescriber as part of their General Medical Services contract.
- (4) For the purposes of this regulation, where a drug ordered on a single prescription form is supplied by instalments, the charge of £3.00 payable for that drug shall be payable upon the supply of the first instalment.
- (5) A contractor, notwithstanding the provisions of his terms of service, shall be under no obligation to provide pharmaceutical services in respect of an order on a prescription form unless he is first paid by the patient any charge required to be made and recovered by paragraph (1) in respect of that order.
- (6) A contractor who makes and recovers a charge under paragraph (1) shall, if so required by the patient, give him a receipt for the amount received on the form provided for the purpose which form shall contain forms of declaration in the support of an application for repayment and information as to whom an application for repayment shall be made.
- (7) Any sum which would otherwise be payable by the Department to a contractor in respect of the provision by him of pharmaceutical services shall be reduced by the amount of any charges which are required to be made and recovered by the preceding provisions of this regulation.

3. Supply of drugs and appliances by the Department

- (1) The Department, when providing to a patient for the purposes of his treatment drugs (otherwise than for administration at a hospital) or appliances, shall, subject to paragraphs (3) and (4), make and recover from the patient
 - (a) in respect of an appliance specified in column 1 of the Schedule, the sum specified in column 2 of the Schedule in respect of that appliance;
 - (b) in respect of the supply of any quantity of a drug, a charge of £3.00.
- (2) Where a charge is paid under paragraph (1) the person making the payment shall on doing so sign a declaration in writing that the relevant charge has been paid.
- (3) No charge shall be made and recovered under this regulation from a patient who
 - (a) is exempt under regulation 4,
 - (b) completes a declaration of entitlement to such exemption, and
 - (c) provides such evidence of entitlement as the Department may reasonably require.

(4) For the purposes of this regulation, where a drug ordered on single written direction is supplied by instalments, the charge of £3.00 payable for that drug shall be payable upon the supply of the first instalment.

4. Exemptions

- (1) Subject to paragraph (3), no charge shall be payable under regulation 2 or 3 by or on behalf of
 - (a) a person who is under 16 years of age;
 - (b) a person who is under 19 years of age and is receiving qualifying full-time education;
 - (c) a person who has attained the age of 60 years;
 - (d) a woman who is pregnant or has given birth within the previous 12 months;
 - (e) a person receiving income support under the Social Security Contributions and Benefits Act 1992 (an Act of Parliament)⁶, as it has effect in the Island⁷, or a dependant of such person;
 - (f) a person in respect of the supply of drugs or appliances for the treatment of a disability which has been accepted for the award of a war disablement pension;
 - (g) a prisoner;
 - (h) a person who is suffering from one or more of the following conditions
 - (i) permanent fistula (including caecostomy, colostomy, laryngostomy or ileostomy) requiring continuous surgical dressing or an appliance;
 - (ii) the following disorders-

forms of hypoadrenalism (including Addison's disease) for which specific substitution therapy is essential; diabetes insipidus and other forms of hypopituitarism; diabetes mellitus, except where treatment is by diet alone;

hypoparathyroidism;

myasthenia gravis;

myxoedema

- (iii) epilepsy requiring continuous anti-convulsive therapy; or
- (iv) a continuing physical disability which prevents the patient from leaving his residence without the help of another person; or

⁶ 1992 c.4

⁷ SD 505/94

- (i) a person holding a valid pre-payment certificate issued by the Department under regulation 5.
- (2) An exemption by reference to age shall be determined by reference to the age on the day on which
 - (a) in the case of pharmaceutical services provided by a contractor, the order for drugs or appliances is presented for dispensing;
 - (b) in any other case, the drugs or appliances are supplied.
- (3) Where a claim to exemption has been made but is not substantiated and in consequence of the claim a charge has not been recovered, the Department shall recover such charge from the person concerned.
- (4) A person who wishes to claim entitlement to exemption under paragraph (1) or (2) shall provide any declaration of entitlement required under regulation 2.

5 Pre-payment certificates

- (1) Subject to the following provisions of this regulation, the Department on payment of the sum specified in paragraph (5) shall as soon as reasonably practicable grant a certificate (a "pre-payment certificate") to any person who duly completes and submits an application for it on a form provided for the purpose.
- (2) A pre-payment certificate shall be valid for a period of either 4 months or 12 months, and an application for such a certificate shall indicate the period for which it is required to be valid.
- (3) A pre-payment certificate which is granted confers on the person to whom it is granted exemption as provided by regulation 4 in respect of drugs and appliances supplied during the period for which it is valid.
- (4) No pre-payment certificate shall be granted unless the application made for it is received less than one month before the date on which its period of validity is to begin.
 - (5) The sum payable on an application under this regulation shall be —
 - (a) £15.00 for a pre-payment certificate valid for 4 months;
 - (b) £42.00 for a pre-payment certificate valid for 12 months.
- (6) Where payment of a prescribed sum has been made under this regulation and, not more than one month after the date on which his pre-payment certificate became valid, the person in respect of whom payment was made
 - (a) becomes a person to whom any of the provisions of regulation 4(1)(a) to(g) applies;
 - (b) dies; or
 - (c) becomes resident in a hospital and thereafter either —

- (i) dies while resident in hospital before the expiry of the prepayment certificate; or
- (ii) remains in hospital until the expiry of the pre-payment certificate,

an application for repayment of that sum may be made, by or on behalf of that person or his estate, in accordance with paragraphs (7) and (8).

- (7) An application under paragraph (6) shall be made to the Department and shall be accompanied by the certificate (where granted) and a declaration in support of the claim, and the claim and any repayment shall be made in such manner and subject to such conditions as the Department may determine.
 - (8) An application under paragraph (6) shall be made —
 - (a) in a case falling within paragraph (6)(a) or (b), not more than 4 months after the date on which the pre-payment certificate became valid;
 - (b) in a case falling within paragraph (6)(c)(i), not more than 3 months after the date of death; or
 - (c) in a case falling within paragraph (6)(c)(ii), not more than 3 months after the date on which the pre-payment certificate expired.

6. Repayment

- (1) Where a charge has been paid under these regulations by or on behalf of a person who was at the time of payment exempt from the requirement to pay that charge, an application for repayment of that charge may be made in accordance with paragraph (2) by or on behalf of that person.
 - (2) The application for repayment shall –
 - (a) be made to the Department;
 - (b) be made in such form and manner as the Department may determine for the applicant, any class of applicant or applicants generally;
 - (c) be made within 3 months from the date on which the drug or appliance was supplied to the applicant;
 - (d) be accompanied by a receipt for the charge paid and a declaration as to the grounds for exemption.
 - (3) The Department shall make arrangements for the repayment of any charge paid under these regulations by a person who is entitled to exemption.

7. Revocation

The National Health Service (Charges for Drugs and Appliances) Regulations 2002⁸ are revoked.

Regulations 2(1)(a) & 3(1)(a).

SCHEDULE

CHARGES FOR APPLIANCES

Appliance	Sum payable
Item of elastic hosiery	£6.40 (ie. £12.60 per pair)
Tights	£12.80
Abdominal or Spinal Support	£32.50
Surgical Brassiere	£21.50
Stock Modacrylic Wig	£53.10
Partial Human Hair Wig	£140.15
Full Bespoke Human Hair Wig	£204.90
Any other appliance	£6.40

MADE 14th October 2004

Member for Health.

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations specify the charges payable for drugs and appliances supplied under Part 2 (primary health services) of the National Health Service Act 2001.

The Regulations increase charges as follows —

- (a) per item on a prescription, from £2.60 to £3.00;
- (b) for a pre-payment certificate for 4 months, from £13.00 to £15.00;
- (c) for a pre-payment certificate for 12 months, from £36.40 to £42.00.

They also increase the charge for certain appliances specified in the Schedule.

The regulations introduce a system by which the Department can refund prescription charges paid by patients who could have claimed an exemption.

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⁸ SD 696/02