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SCOTTISH STATUTORY INSTRUMENTS

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**2001 No. 430**

**The National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2001**

**Citation and commencement**

1. These Regulations may be cited as the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2001 and shall come into force on 14th December 2001.

**Interpretation**

2.—(1) In these Regulations—

“the Act” means the National Health Service (Scotland) Act 1978;

“accepted disablement” means physical or mental injury or disease which is accepted by the Scottish Ministers as attributable to or aggravated by service in the armed forces of the Crown or such other service as they may determine;

“appliance” means an appliance, other than a contraceptive appliance, which is a listed appliance within the meaning of section 27(1) of the Act;

“Board” means a Health Board constituted under section 2 of the Act;

“chemist” includes any person, other than a doctor, providing pharmaceutical services;

“dentist” means a registered dental practitioner;

“doctor” means a registered medical practitioner;

“drugs” includes medicines but does not include contraceptive substances;

“elastic hosiery” means anklet, legging, knee-cap, below-knee or thigh stocking;

“exemption” means any remission granted under or by virtue of these Regulations;

“exemption certificate” means a certificate issued pursuant to these Regulations authorising a person to claim exemption from charges payable under these Regulations;

“the General Medical Services Regulations” means the National Health Service (General Medical Services) (Scotland) Regulations 1995(1);

“medical list” has the meaning assigned to it by regulation 4(1) of the General Medical Services Regulations;

“nurse prescriber” means a nurse or health visitor of a description specified in paragraph (2);

“out-patient” means a person receiving treatment under the Act otherwise than under Part II of the Act and who is not for the purpose of receiving that treatment resident in a hospital;

“patient” means—

- (a) any person for whose treatment a doctor is responsible under his terms of service or in connection with a pilot scheme; or

(b) any person who applies to a chemist for the provision of pharmaceutical services, and includes for the purposes of these Regulations a person acting on behalf of such a person;

“pharmaceutical services” means services provided under section 27 of the Act;

“pilot scheme” shall be construed in accordance with section 1(1) of the National Health Service (Primary Care) Act 1997(2);

“prescription form” means a form on which the provision of pharmaceutical services may be ordered by a Board or an NHS trust or by a doctor or dentist pursuant to the provisions of their terms of service or a dentist performing personal dental services in accordance with a pilot scheme under Part I of the National Health Service (Primary Care) Act 1997, or by a nurse prescriber and which contains on its reverse side a form of declaration of entitlement to exemption;

“terms of service” has the meaning respectively in respect of a doctor, a chemist or a dentist assigned to it in the General Medical Services Regulations, the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995(3) or the National Health Service (General Dental Services) (Scotland) Regulations 1996(4);

“the Travelling Expenses and Remission of Charges Regulations” means the National Health Service (Travelling Expenses and Remission of Charges) (Scotland) Regulations 1988(5);

“treatment” includes examination and diagnosis.

(2) The specified description of a nurse or health visitor mentioned in the definition of “nurse prescriber” in paragraph (1) is—

(a) a person who is registered in Part 1 or 12 of the register maintained under the Nurses, Midwives and Health Visitors Act 1997(6) (referred to below in this paragraph as “the professional register”), has a district nursing qualification additionally recorded in the professional register maintained under rule 11 of the Nurses, Midwives and Health Visitors Rules 1983(7), and is, at the time of ordering the listed drug or medicine or listed appliance—

(i) employed as a district nurse by a Board or an NHS trust; or

(ii) employed as a nurse by a doctor whose name is included in a medical list or who, at that time, is assisting in the performance of personal medical services under a pilot scheme; or

(b) a person who is registered in Part 11 of the professional register as a health visitor and is, at the time of ordering the listed drug or medicine or listed appliance—

(i) employed as a health visitor by a Board or NHS trust; or

(ii) employed as a health visitor by a doctor whose name is included in a medical list or who, at that time, is assisting in the performance of personal medical services under a pilot scheme,

against whose name (in each case) is recorded in the professional register an annotation signifying that that person is qualified to order drugs, medicines and appliances for patients.

(3) For the purpose of these Regulations—

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(2) 1997 c. 46.

(3) S.I. 1995/414 to which there are amendments not relevant to these Regulations.

(4) S.I. 1996/177 to which there are amendments not relevant to these Regulations.

(5) S.I. 1988/546 as amended by S.I. 1989/393 and 616, 1990/551, 917 and 1665, 1991/575, 1992/754, 1993/642 and 2049, 1995/700 and 2381, 1996/429 and 2391, 1997/1012 and 2455 and 1988/2772 and S.S.I. 1999/63 and 2000/79.

(6) 1997 c. 24.

(7) Approved by S.I. 1983/873 to which there are amendments not relevant to these Regulations.

- (a) the supply of quantities of the same drug in more than one container against an order on one prescription form shall be deemed to be the supply of only one quantity of a drug; and
- (b) the supply against an order on one prescription form of more than one appliance of the same type or the supply against an order on one prescription form of two or more component parts of the same appliance shall be deemed to be the supply of only one appliance, however any piece of elastic hosiery shall be deemed to be a separate appliance.

(4) Unless the context otherwise requires, any reference in these Regulations to a numbered regulation or Schedule is a reference to the regulation in, or as the case may be, the Schedule to these Regulations which bears that number, and any reference in a regulation to a numbered paragraph is a reference to the paragraph bearing that number in that regulation.

### **Supply of drugs and appliances by chemists**

**3.—(1)** A chemist who provides pharmaceutical services to a patient shall make and recover from the patient—

- (a) in respect of the supply of an appliance specified in column 1 of Schedule 1 a charge in the sum specified in column 2 of Schedule 1 in respect of that appliance; and
- (b) in any other case, in respect of the supply of each quantity of a drug and each appliance not so specified, a charge in the sum of £6.10;

except where a declaration of entitlement to exemption on the prescription form is duly completed by or on behalf of the patient.

(2) For the purposes of this regulation, where a quantity of a drug ordered on one prescription form is ordered to be supplied by instalments during a period of not more than 14 days, only one charge shall be payable and it shall be payable upon the supply of the first instalment.

(3) A chemist, 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 the chemist is first paid by the patient the charge payable under paragraph (1)(a) or (1)(b) or the exception set out in paragraph (1) is applicable.

(4) A chemist who makes and recovers a charge under paragraphs (1) or (2) shall, if so required by the patient, give the patient a receipt for the amount received on a form provided for the purpose by the Board which contains forms of declaration in support of an application for repayment.

(5) Any sum which a Board is under a duty to pay or cause to be paid to a chemist in respect of the provision by the chemist of pharmaceutical services, other than such provision to which the exception set out in paragraph (1) applies, shall be reduced by the sum specified in paragraph (1)(b) in respect of each quantity of a drug supplied and by the sum specified in paragraph (1)(b), or as the case may require, the sum specified in column 2 of Schedule 1 in respect of each appliance supplied as part of such services.

### **Supply of drugs and appliances by doctors**

**4.—(1)** A doctor, who provides pharmaceutical services to a patient in pursuance of the provisions of regulation 34 of the General Medical Services Regulations (and otherwise than under paragraph 15(1) of Schedule 1 to those Regulations) shall make and recover from that patient—

- (a) in respect of the supply of an appliance specified in column 1 of Schedule 1 a charge in the sum specified in column 2 of Schedule 1 in respect of that appliance; and
- (b) in any other case, in respect of the supply of each quantity of a drug and each appliance not so specified, a charge in the sum specified in regulation 3(1)(b),

except where the patient or a person on the patient's behalf declares that the patient is entitled to exemption.

(2) For the purposes of this regulation where a doctor supplies a quantity of a drug by instalments during a period of not more than 14 days, only one charge shall be payable and it shall be payable upon the supply of the first instalment.

(3) A doctor shall be under no obligation to supply drugs or appliances in respect of which the doctor is required by the provisions of paragraph (1) to make and recover a charge, unless the doctor is first paid by the patient the charge prescribed by paragraph (1)(a) or (1)(b), or the exception set out in paragraph (1) is applicable.

(4) A doctor shall as soon as practicable after the end of each month send a sum of money equal to the total of the charges required to be made and recovered by the doctor pursuant to the provisions of paragraph (1) during that month to the Board on whose medical list the doctor is included, or, if the doctor is included on more than one medical list, to the Board which pursuant to the provisions of the Statement published under regulation 35 of the General Medical Services Regulations causes payment to be made to the doctor for the provision of general medical services on behalf of all the Boards concerned.

(5) A doctor who makes and recovers a charge under paragraphs (1) or (2) shall, if so required by the patient, give the patient a receipt for the amount received on a form provided for the purpose by the Board which contains forms of declaration in support of an application for repayment.

### **Supply of drugs and appliances to out-patients**

**5.—**(1) A Board or an NHS trust which at a hospital supplies to an out-patient drugs (otherwise than for administration in the hospital) or appliances for the purposes of the patient's treatment, shall make and recover from the out-patient—

- (a) in respect of the supply of an appliance specified in column 1 of Schedule 1 or of Schedule 2 a charge in the sum specified in column 2 of Schedule 1 or of Schedule 2 in respect of that appliance; and
- (b) in respect of the supply of each quantity of a drug and each appliance not so specified, a charge in the sum specified in regulation 3(1)(b).

(2) For the purposes of this regulation only one charge in respect of each quantity of a drug supplied by a hospital or by a chemist against an order on one prescription form shall be payable notwithstanding that such quantity is by order of the prescriber to be supplied on more than one day during a period of 14 days.

(3) A Board or an NHS trust which makes and receives a charge under this regulation shall, if so required by the patient, give the patient a receipt for the amount paid on a form which contains forms of declaration in support of an application for repayment.

### **Fabric supports and wigs**

**6.—**(1) A Board or an NHS trust which, otherwise than under Part II of the Act, supplies to a patient for the purposes of the patient's treatment an appliance of a description specified in column 1 of Schedule 3 shall make and recover from the patient a charge in the sum specified in column 2 of Schedule 3 in respect of that appliance.

(2) A Board or an NHS trust which makes and recovers a charge under this regulation shall, if so required by the patient making the payment, give the patient a receipt for the amount received.

(3) No charge under this regulation shall be payable by or on behalf of a patient to whom the Scottish Ministers have issued an exemption certificate in respect of treatment for accepted disablement in respect of the supply of an appliance which the patient requires for the purpose of the treatment of that disablement.

(4) Where a patient has paid a charge which, but for paragraph (3), would be authorised by paragraph (1) the patient may claim a refund of that charge by presenting to the Board or, as the case may be, the NHS trust the receipt for it together with—

- (a) the certificate mentioned in paragraph (3); and
- (b) if the patient was referred by a doctor to the Board or, as the case may be, the NHS trust for treatment, either—
  - (i) a certificate from the doctor certifying that it was for the accepted disablement; or
  - (ii) a statement that such a certificate was surrendered to the Board or, as the case may be, the NHS trust on or before the supply of the appliance.

(5) The Board or, as the case may be, the NHS trust, if satisfied by the evidence so produced that the charge to which the receipt relates was not properly payable, shall repay to the patient the amount of the charge and return any certificate to which paragraph (3) refers which the patient may have submitted.

### **Exemptions**

7.—(1) Subject to the provisions of paragraphs 1(1) and 4 of Schedule 11 to the Act and to the following provisions of this regulation, no charge shall be payable under these Regulations other than regulation 6 by—

- (a) a person who has not attained the age of 16 years;
- (b) a person who has not attained the age of 19 years and is receiving qualifying full time education within the meaning of paragraph 7 of Schedule 11 to the Act<sup>(8)</sup>;
- (c) a person who has attained the age of 60 years;
- (d) a woman to whom a Board has issued an exemption certificate on the ground that she is an expectant mother or has within the last twelve months given birth to a live child or a child registrable as still-born under the Registration of Births, Deaths and Marriages (Scotland) Act 1965<sup>(9)</sup>;
- (e) a person to whom a Board has issued an exemption certificate on the ground that the person 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) forms of hypoadrenalism (including Addison's disease) for which specific substitution therapy is required,
    - 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;
  - (iv) a continuing physical disability which prevents the patient from leaving a residence without the help of another person;
- (f) a person to whom the Scottish Ministers have issued a certificate in respect of the supply of drugs and appliances for the treatment of accepted disablement but only in respect of those supplies to which the certificate relates;

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<sup>(8)</sup> Paragraph 7 of Schedule 11 was inserted by the Health Services Act 1980 (c. 53), Schedule 5, paragraph 8.

<sup>(9)</sup> 1965 c. 49.

- (g) a person to whom a certificate has been granted pursuant to regulations having effect under or by virtue of section 69(2) of the Act.
- (2) No exemption from a charge payable under these Regulations shall be granted unless—
- (a) in the case of a charge payable to a chemist, a declaration of entitlement to exemption on the prescription form presented to the chemist is duly completed by or on behalf of the person claiming exemption; or
  - (b) in the case of a charge payable to a doctor, a declaration of entitlement to exemption, which shall be in writing if the doctor so requires, is made to that doctor; or
  - (c) in the case of a charge payable to a Board or, as the case may be, to an NHS trust under regulation 5, the person claiming exemption provides such evidence as that Board or, as the case may be, that NHS trust may reasonably require that the person is entitled to such exemption.
- (3) A person who wishes to claim exemption pursuant to the provisions of paragraph (1)(d) or (1)(e) shall apply for an exemption certificate to the Board on a form supplied by the Board for that purpose.
- (4) A Board on being satisfied that an applicant is entitled to exemption pursuant to the provisions of paragraph (1)(d), shall issue an exemption certificate which shall have effect in the case of an expectant mother until the end of her pregnancy, and
- (a) where she gives birth to a child registrable as still-born under the Registration of Births, Deaths and Marriages (Scotland) Act 1965, until the end of the period of twelve months beginning with the expected date of confinement, or
  - (b) in the case of a mother who has given birth to a live child, until the end of the period of twelve months beginning with the date of birth of that child.
- (5) A Board shall issue to the applicant an exemption certificate which shall have effect for such period as they may determine, on being satisfied that the applicant is not entitled to exemption under the provisions of paragraph (1)(a), (1)(b) or (1)(c), and is entitled to exemption in pursuance of the provisions of paragraph (1)(e).
- (6) Where a claim to exemption has been made but is not substantiated and in consequence of that claim a chemist, a doctor, a Board or, as the case may be, an NHS trust has not recovered a charge in respect of the supply of any drugs or appliances, a Board or NHS trust shall recover such charge from the person concerned.
- (7) Any claim to exemption by reference to age or the validity of a certificate shall be determined by reference to age or validity on the date on which any order for drugs or appliances is presented for dispensing, or, as the case may be, drugs or appliances are supplied by a doctor, a Board or, as the case may be, an NHS trust.
- (8) The charges which may be made and recovered by virtue of these Regulations are subject to the provisions of regulations made under section 75A of the Act<sup>(10)</sup> providing for remission or repayment<sup>(11)</sup>.

### **Pre-payment certificates**

**8.—(1)** Subject to the following provisions of this regulation, a Board on payment of the sum prescribed by paragraph (5) shall as soon as reasonably practicable grant a certificate (in these Regulations referred to as pre-payment certificate) to any person who duly completes and submits an application therefor on a form provided for the purpose by the Board.

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<sup>(10)</sup> Section 75A was inserted by the Social Security Act 1988 (c. 7), section 14(2).

<sup>(11)</sup> See S.I. 1988/546, as amended by S.I. 1989/393 and 616, 1990/551, 917 and 1665, 1991/575, 1992/754, 1993/642 and 2049, 1995/700 and 2381, 1996/429 and 2391, 1997/1012 and 2455 and 1988/2772 and S.S.I. 1999/63 and 2000/79

(2) A pre-payment certificate shall be valid for a period of either 4 months or 12 months and an application under paragraph (1) for such a certificate shall indicate the period for which it is required to be valid.

(3) The payment of a sum prescribed under this regulation shall not be deemed to be the payment of a charge under these Regulations.

(4) No certificate shall be issued under this regulation unless the application made therefor is received less than one month before the date on which its period of validity is to begin.

(5) For the purpose of this regulation the sum prescribed shall be £31.90 for a pre-payment certificate valid for 4 months and £87.60 for such a certificate valid for 12 months.

(6) Where a payment of a sum prescribed under this regulation has been made and, not more than one month after the date on which the person's 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 7(1)(b) to (f) applies; or
- (b) becomes a person entitled to remission under regulation 3 of the Travelling Expenses and Remission of Charges Regulations; or
- (c) dies; or
- (d) becomes resident in a hospital and thereafter either—
  - (i) dies while resident in hospital before the expiry of the pre-payment 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 that person's estate, in accordance with paragraphs (13) to (15).

(7) Where a payment of a sum prescribed under this regulation has been made and where, on or after 14th December 2001, the person in respect of whom the payment was made dies or becomes resident in hospital and thereafter dies during the relevant period as defined in paragraph (9) an application for a refund may be made, by or on behalf of that person's estate, in accordance with paragraphs (13) to (15).

(8) The refund referred to in paragraph (7) shall be calculated as follows:

- (a) in the case of a pre-payment certificate valid for 4 months, 1/4 of the sum prescribed under this regulation paid for each complete month after the date of death during which the pre-payment certificate would have remained valid but for that death;
- (b) in the case of a pre-payment certificate valid for 12 months, 1/12 of the sum prescribed under this regulation paid for each complete month after the date of death during which the pre-payment certificate would have remained valid but for that death;

and for the purposes of these calculations a complete month is a month beginning on the date of death and ending on the date immediately preceding that date in the following month.

(9) In paragraph (7) "the relevant period" means the period of validity of the pre-payment certificate excluding the month in respect of which an application under paragraph (6) may be made.

(10) Where a payment of a prescribed sum in respect of a pre-payment certificate valid 12 months has been made and where, on or after 14th December 2001, and during the relevant period defined in paragraph (12), the person in respect of whom the payment was made—

- (a) becomes a person to whom any of the provisions of regulation 7(1)(b) to (f) applies, or
- (b) becomes a person entitled to remission under regulation 3 of the Travelling Expenses and Remission of Charges Regulations

an application for a refund may be made, by or on behalf of that person in accordance with paragraphs (13) to (15).

(11) The refund referred to in paragraph (10) shall be for the sum which is the difference between the sum prescribed under this regulation and paid and the sum which was prescribed for a pre-payment certificate valid for four months on the date that the prescribed sum was paid.

(12) In paragraph (10) “the relevant period” means the period of 3 months immediately following the month in respect of which a claim under paragraph (6) may be made.

(13) Applications under this regulation for repayments or refunds shall be made to the Board which received the sum prescribed under this regulation and shall be accompanied by the certificate (where granted) and a declaration in support of the application and any repayment shall be made in such manner and subject to such conditions as the Scottish Ministers may determine.

(14) Subject to paragraph (15) an application under this regulation shall be made where the person in respect of whom the payment of the sum prescribed under this regulation was made—

(a) dies or becomes resident in hospital and thereafter dies, within 24 months of the date of death; or

(b) has a pre-payment certificate valid for 4 months and becomes a person—

(i) to whom any of the provisions of regulation 7(1)(b) to (f) apply, or

(ii) entitled to remission under regulation 3 of the Travelling Expenses and Remission of Charges Regulations

within four months of the date on which the pre-payment certificate ceased to be valid; or

(c) has a pre-payment certificate valid for 12 months and becomes a person—

(i) to whom any of the provisions of regulation 7(1)(b) to (f) apply, or

(ii) entitled to remission under regulation 3 of the Travelling Expenses and Remission of Charges Regulations

within seven months of the date on which the pre-payment certificate ceased to be valid; or

(d) becomes resident in hospital and remains there until the expiry of a pre-payment certificate, within 3 months of the date of expiry.

(15) Where an application under this regulation is made outside the time limits specified in paragraph (14) in respect of a death which occurs on or after 14th December 2001 or in respect of a person who becomes a person to whom paragraph (14)(b) to (d) applies on or after 14th December 2001, the Board shall accept the application if the Scottish Ministers are satisfied that the delay was for good cause.

## Repayments

9.—(1) Where a charge has been paid under these Regulations by or on behalf of a person who, by virtue of regulation 7, was at the time of payment eligible for exemption from that charge, a claim for repayment of that charge may, subject to the provisions of this regulation, be made by or on behalf of that person.

(2) A claim under this regulation for repayment of charges paid shall be made on a form provided for the purpose by the Scottish Ministers and which shall be accompanied by the appropriate receipt and the appropriate declaration in support of the claim.

(3) A claim under this regulation for repayment shall be made not less than one month but not more than three months after the date on which the charge was paid.

## Application

10. These Regulations shall apply only where drugs or appliances are supplied on or after 14th December 2001 except that—



- (a) regulation 6 shall apply where the examination or first examination leading to the supply of the specified appliance takes place on or after 14th December 2001;
- (b) regulation 8 shall apply where the application referred to in paragraph (1) of that regulation is received on or after 14th December 2001.

### **Revocations**

**11.** The Regulations specified in column 1 of Schedule 4 are hereby revoked to the extent specified in column 3 of that Schedule.

St Andrew's House,  
Edinburgh  
21st November 2001

*MALCOLM CHISHOLM*  
Authorised to sign by the Scottish Ministers