STATUTORY INSTRUMENTS

2000 No. 620

The National Health Service (Charges for Drugs and Appliances) Regulations 2000

Citation, commencement and extent

- 1.—(1) These Regulations may be cited as the National Health Service (Charges for Drugs and Appliances) Regulations 2000 and shall come into force on 1st April 2000.
 - (2) These regulations extend to England only.

Interpretation

- 2.—(1) In these Regulations, unless the context otherwise requires—
 - "the Act" means the National Health Service Act 1977;
 - "accepted disablement" means physical or mental injury or disease which is accepted by the Secretary of State as attributable to or aggravated by service in the armed forces of the Crown or such other service as he may determine;
 - "appliance" means a listed appliance within the meaning of section 41 of the Act but does not include a contraceptive appliance;
 - "chemist" includes any person, other than a doctor, providing pharmaceutical services;
 - "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 these regulations from charges payable under these regulations;
 - "exemption certificate" has the meaning assigned to it by regulation 8(1);
 - "medical list" means the list, prepared under section 29 of the Act, of medical practitioners who have undertaken to provide general medical services;
 - "nurse prescriber" means a nurse or health visitor of a description specified in paragraph (2); "patient" means
 - (a) any person for whose treatment a doctor is responsible under his terms of service or in connection with a pilot scheme;
 - (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;
 - (c) any person who seeks information or treatment from a walk-in Centre;
 - "pilot scheme" shall be construed in accordance with section 1(1) of the National Health Service (Primary Care) Act 1997(1);
 - "pre-payment certificate" has the meaning assigned to it by regulation 9(1);

"prescription form" means a form provided by a Health Authority, an NHS trust or a Primary Care Trust and issued by a doctor, dentist or nurse prescriber to enable a person to obtain pharmaceutical services and includes a prescription form provided and issued under equivalent arrangements having effect in Scotland, Wales or Northern Ireland;

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

"the Travelling Expenses and Remission of Charges Regulations" means the National Health Service (Travelling Expenses and Remission of Charges) Regulations 1988(2);

"treatment" includes examination and diagnosis;

- "Walk-in Centre" means a centre at which information and treatment for minor conditions is provided to the public under arrangements made by or on behalf of the Secretary of State.
- (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(3) (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 Rule 1983(4), and is, at the time of ordering the listed drug or medicine or listed appliance—
 - (i) employed as a district nurse by a Health Authority, an NHS trust or a Primary Care Trust or by a local authority in connection with arrangements under section 31(2)(c) of the Health Act 1999;
 - (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
 - (iii) assisting, in the capacity of a nurse, in the provision of services in a Walk-in-Centre;
 - (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 nurse by a Health Authority, an NHS trust or a Primary Care Trust or by a local authority in connection with arrangements under section 31(2)(c) of the Health Act 1999;
 - (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 pilot scheme; or
 - (iii) assisting, in the capacity of a nurse, in the provision of services in Walk-in-Centre; against whose name (in each case) is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances for patients.
 - (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.

⁽²⁾ S.I. 1988/551 as amended by S.I. 1989/394, 517 and 614, 1990/548, 918 and 1661, 1991/557, 1992/1104, 1993/608, 1995/642 and 3252, 1996/410, 1346 and 2362, 1997/748 and 2393, 1998/2417, and 1999/767 and 2507 and 2000/621.

^{(3) 1997} c. 24

⁽⁴⁾ S.I. 1983/873 to which there are amendments.

(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 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, subject to paragraph (3), make and recover from that patient—
 - (a) in respect of an item of elastic hosiery a charge of £6.00, that is to say a charge of £12.00, per pair;
 - (b) in respect of the supply of each other appliance and of each quantity of a drug, a charge of £6.00.
- (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.
 - (3) No charge shall be made and recovered under paragraph (1) where—
 - (a) there is exemption under regulation 7 and a declaration of entitlement to exemption on the prescription form is duly completed by or on behalf of the patient;
 - (b) there is entitlement to remission of the charge under regulation 3 of the Travelling Expenses and Remission of Charges Regulations and a declaration of entitlement to remission on the prescription form is duly completed by or on behalf of the patient;
 - (c) the patient is resident in a school or institution the name of which is inserted on the prescription form by a doctor under his terms of service or in connection with a pilot scheme.
- (4) For the purposes of this regulation, where a drug ordered on a single prescription form is supplied by instalments, the charge of £6.00 payable for that drug shall be payable upon the supply of the first instalment.
- (5) 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 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 chemist 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 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 a Health Authority to a chemist 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.

Supply of drugs and appliances by doctors

- **4.**—(1) A doctor who provides pharmaceutical services to a patient shall, subject to paragraph (3), make and recover from that patient—
 - (a) in respect of an item of elastic hosiery a charge of £6.00, that is to say a charge of £12.00, per pair;
 - (b) in respect of the supply of each other appliance and of each quantity of a drug, a charge of £6.00.
- (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.

- (3) No charge shall be made and recovered under paragraph (1) where-
 - (a) there is exemption under regulation 7 and a declaration of entitlement to exemption on the prescription form is duly completed by or on behalf of the patient;
 - (b) there is entitlement to remission of the charge under regulation 3 of the Travelling Expenses and Remission of Charges Regulations and a declaration of entitlement to remission on the prescription form is duly completed by or on behalf of the patient;
 - (c) the drugs or appliances are supplied in respect of two or more persons in a school or institution in which at least 20 persons are normally resident of whom at least 10 are his patients.
- (4) For the purposes of this regulation, where a drug ordered on a single prescription form is supplied by instalments, the charge of £6.00 payable for that drug shall be payable upon the supply of the first instalment.
- (5) A doctor shall be under no obligation to provide pharmaceutical services for which a charge is required to be made and recovered by paragraph (1) unless he is first paid the amount of that charge by the patient.
- (6) A doctor 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 support of an application for repayment and information as to whom an application for repayment shall be made.
- (7) 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 him under paragraph (1) during that month, as the case may be—
 - (a) to the Health Authority on whose medical list he is included, or
 - (b) if he is included on more than one medical list, to the Health Authority which, pays him for the provision of general medical services on behalf of all the Health Authorities concerned, or
 - (c) if the doctor is performing personal medical services in connection with a pilot scheme, to the Health Authority or Primary Care Trust which is a party to that pilot scheme.
- (8) Nothing in this regulation shall authorise the payment of a charge where the drug or appliance supplied either—
 - (a) is needed for immediate treatment and no order for the drug or appliance is made on a prescription form; or
 - (b) is administered or applied to the patient by the doctor personally.

Supply of drugs and appliances by Health Authorities, NHS trusts and Primary Care Trusts

- **5.**—(1) A Health Authority, an NHS trust or a Primary Care Trust which supplies 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 item of elastic hosiery a charge of £6.00, that is to say a charge of £12.00 per pair;
 - (b) in respect of an appliance specified in column (1) of Schedule 1, the charge specified in relation to it in column (2) of that Schedule;
 - (c) in respect of tights, a charge of £12.00;
 - (d) in respect of the supply of each other appliance and of each quantity of a drug, a charge of £6.00.

- (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 is exempt—
 - (a) under paragraph 1(1)(a) to (d) of Schedule 12 to the Act,
 - (b) under regulation 7, or
 - (c) by reason of being entitled to remission under regulation 3 of the Travelling Expenses and Remission of Charges Regulations,

and who, in the case described in paragraph 1(1)(c) of Schedule 12 to the Act and in the cases described in sub-paragraphs (b) and (c), completes a declaration of entitlement to such exemption or remission and provides such evidence of entitlement as the Health Authority, NHS trust or Primary Care trust may reasonably require.

- (4) A partially remitted charge shall be made and recovered under this regulation from a patient who is entitled to partial remission under regulation 7(4) if a declaration in writing is provided that the relevant part of the charge has been paid and a declaration of entitlement and such other evidence of entitlement, to partial remission as may be required, is provided.
- (5) For the purposes of this regulation, where a drug ordered on a single written direction is supplied by instalments, the charge of £6.00 payable for that drug shall be payable upon the supply of the first instalment.
- (6) A Health Authority, NHS trust or Primary Care Trust which makes and recovers a charge under this regulation shall, if so required by the patient, give him a receipt for the amount received on a form which shall contain forms of declaration in support of an application for repayment and information as to whom an application for repayment shall be made.

Supply of drugs and appliances at Walk-in-Centres

- **6.**—(1) Where drugs or appliances are supplied to a patient, for the purposes of his treatment by a doctor or nurse prescriber at a Walk-in-Centre the Health Authority, NHS trust, Primary Care Trust or other person responsible for the management of the Centre shall, except in the case of drugs administered or appliances fitted at the Centre and subject to paragraphs (3) and (4), make and recover from the patient—
 - (a) in respect of an item of elastic hosiery a charge of £6.00, that is to say a charge of £12.00 per pair;
 - (b) in respect of the supply of each other appliance and each quantity of a drug, a charge of £6.00.
- (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 is exempt-
 - (a) under paragraph 1(1)(a) to (d) of Schedule 12 to the Act,
 - (b) under regulation 7, or
 - (c) by reason of being entitled to remission under regulation 3 of the Travelling Expenses and Remission of Charges Regulations,

and who, in the case described in paragraph 1(1)(c) of Schedule 12 to the Act and in the cases described in sub-paragraphs (b) and (c), completes a declaration of entitlement to such exemption or remission and provides such evidence of entitlement as the Health Authority, NHS trust or Primary Care Trust or other person supplying the drug or appliance 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 £6.00 payable for that drug shall be payable upon the supply of the first instalment.
- (5) A Health Authority, NHS trust, Primary Care Trust or other person making and recovering a charge under this regulation shall, if so required by a patient, give him a receipt for the amount received on a form which shall contain forms of declaration in support of an application for repayment and information as to whom an application for repayment shall be made.

Exemptions

- 7.—(1) Subject to paragraph (3), no charge shall be payable under regulations 3, 4 or 6 by—
 - (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 within the meaning of paragraph 7 of Schedule 12 to the Act;
 - (c) a person who has attained the age of 60 years;
 - (d) a woman with a valid exemption certificate issued by a Health Authority 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 Births and Deaths Registration Act 1953(5) or with a valid exemption certificate issued under equivalent arrangements having effect in Scotland, Wales or Northern Ireland;
 - (e) a person with a valid exemption certificate issued by a Health Authority on the ground that he 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;
- (iv) a continuing physical disability which prevents the patient from leaving his residence without the help of another person;
- or by a person with a valid exemption certificate issued under equivalent arrangements having effect in Scotland, Wales or Northern Ireland;
- (f) a person with a valid exemption certificate issued by the Secretary of State in respect of the supply of drugs and appliances for the treatment of accepted disablement, but in either case only in respect of those supplies to which the certificate relates;
- (g) a person with a valid pre-payment certificate or with a valid pre-payment certificate granted under equivalent arrangements having effect in Scotland, Wales or Northern Ireland.
- (2) Subject to paragraph (3), no charge shall be payable under regulation 5–

- (a) in respect of the supply of an appliance specified in column (1) of Schedule 1 by a person of a description specified in paragraph (1)(f);
- (b) in respect of the supply of an appliance not so specified or of tights or of drugs, by a person of a description specified in any of sub-paragraphs (c) to (g) of paragraph (1).
- (3) A person who wishes to claim entitlement to exemption under paragraph (1) or (2) shall provide any declaration of entitlement required under regulations 3(3) or 4(3) and any declaration or evidence of entitlement required under regulations 5(3) or 6(3).
- (4) A charge referred to in column (1) of Schedule 1 shall, in the case of a person referred to in regulation 5 of the Travelling Expenses and Remission of Charges Regulations, be remitted to the extent specified in that regulation.
- (5) Where a charge is remitted in part under paragraph (4) the person making the part payment shall on doing so sign a declaration in writing that the relevant part of the charge has been paid and complete a declaration of entitlement, and provide such other evidence of entitlement, to partial remission as may be required.
- (6) An exemption by reference to age or the validity of an exemption certificate shall be determined by reference to the age or validity on the day on which—
 - (a) in the case of pharmaceutical services provided by a chemist, the order for drugs or appliances is presented for dispensing;
 - (b) in any other case, the drugs or appliances are supplied.
- (7) 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 Health Authority or, where the drugs or appliances were supplied by an NHS trust or a Primary Care Trust, that NHS trust or that Primary Care Trust, shall recover such charge from the person concerned.

Certificates of exemption—application and issue

- **8.**—(1) A person who wishes to claim exemption under the provisions of regulation 7(1)(d), (e) or (f) shall apply for a certificate conferring exemption (in these Regulations referred to as an "exemption certificate") to the Health Authority in the case of an exemption under sub-paragraph (d) or (e) on a form supplied for that purpose and in the case of an exemption under sub-paragraph (f) to an office of the Department of Social Security on a form supplied for that purpose by the Secretary of State.
- (2) A Health Authority, on being satisfied that an applicant is entitled to exemption under paragraph (1)(d), shall issue an exemption certificate which shall be valid—
 - (a) in the case of an expectant mother until the end of her pregnancy and, where she gives birth to a live child or a child registrable as still-born under the Births and Deaths Registration Act 1953, until the end of the period of twelve months beginning with the expected date of confinement;
 - (b) in the case of a mother who has given birth to a child, until the end of the period of twelve months beginning with the date of birth of that child.
- (3) A Health Authority, on being satisfied that an applicant, not being a person entitled to exemption under the provisions of regulation 7(1)(a), (b) or (c), is entitled to exemption under regulation 7(1)(e) shall issue to the applicant an exemption certificate which shall be valid for such period as it may determine.
- (4) The Secretary of State, on being satisfied that an applicant is entitled to exemption under regulation 7(1)(f), shall issue to the applicant an exemption certificate which shall be valid for such period as he may determine.

Pre-payment certificates

- **9.**—(1) Subject to the following provisions of this regulation, a Health Authority on payment of the relevant sum prescribed by paragraph (5) shall as soon as reasonably practicable grant a certificate (in these regulations referred to as 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 four months or twelve 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 7(1)(g) 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) For the purposes of this regulation the prescribed sum shall be £31.40 for a pre-payment certificate valid for 4 months and £86.20 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 7(1)(b) to (f) applies;
 - (b) or 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 his estate, in accordance with paragraphs (7) and (8).
- (7) An application under paragraph (6) shall be made to the Health Authority which granted the certificate 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 Secretary of State may determine.
 - (8) An application under paragraph (6) shall be made-
 - (a) in a case falling within paragraph (6)(a), (b) or (c), not more than four months after the date on which the pre-payment certificate became valid;
 - (b) in a case falling within paragraph (6)(d)(i), not more than three months after the date of death; or
 - (c) in a case falling within paragraph (6)(d)(ii), not more than three months after the date on which the pre-payment certificate expired.

Repayment of charges

- 10.—(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 person or body specified in the receipt which is given under regulation 3(6), 4(6), 5(6) or 6(5) as being the person or body to whom application for repayment of charges is to be made;
- (b) be made in such form and manner as the Secretary of State 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 or within such period as Secretary of State may, for good cause, allow;
- (d) be accompanied by the receipt for the charge paid and a declaration as to the grounds of exemption.
- (3) In the case of a charge under regulation 5 in respect of an appliance specified in column (1) of Schedule 1, the application shall be accompanied by the exemption certificate referred to in regulation 7(1)(f) and, if the patient was referred by a doctor to the Health Authority, NHS trust or Primary Care Trust for treatment, either—
 - (a) a certificate from the doctor certifying that the treatment was for accepted disablement; or
 - (b) a statement that such a certificate was surrendered to the Health Authority, NHS trust or Primary Care Trust before the supply of the appliance.
- (4) The Secretary of State shall make arrangements for the repayment of any charge paid under these Regulations by a person who is entitled to exemption.

Arrangements between NHS bodies and Local Authorities

11. Any arrangements made by virtue of section 31(2)(c) of the Health Act 1999(6) (arrangements between NHS bodies and local authorities) for or in connection with the exercise by a local authority of any functions of a Health Authority, NHS trust or Primary Care Trust shall not affect any power or duty to recover charges in respect of services provided in the exercise of those functions and these Regulations shall apply as if the functions were exercised by the Health Authority, NHS trust or Primary Care Trust with which the arrangements were made.

Transitional Provision

12. Where an application under regulation 9 for a pre-payment certificate was received before the coming into force of these Regulations the prescribed sum payable shall be that which applied immediately before the coming into force of these Regulations.

Revocations

13. The Regulations specified in column (1) of Schedule 2 are hereby revoked in relation to England to the extent specified in column (3) of that Schedule.

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under-Secretary of State,
Department of Health

9th March 2000