# STATUTORY INSTRUMENTS

2007 No. (W.)

# NATIONAL HEALTH SERVICE, WALES

National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

- 1. These Regulations revoke and replace, with amendments, the National Health Service (Charges for Drugs and Appliances) Regulations 2001(1) as amended.
- 2. Accordingly, these Regulations abolish charges in respect of drugs and appliances supplied to patients registered with GPs in Wales, or registered with GPs in England but holding valid entitlement cards, where such drugs and appliances are supplied by chemists providing pharmaceutical services (regulation 3), by doctors providing pharmaceutical services (regulation 4), by Local Health Boards and NHS trusts (regulation 5) and at walk-in centres (regulation 6) and when they are supplied in accordance with patient group directions (regulation 7). Regulations 3 and 4 further provide for charges for drugs and appliances to any patients other than patients registered with GPs in Wales or registered with GPs in England but holding valid entitlement cards.
- **3.** Save in the circumstances outlined in paragraph 2 above, these Regulations provide for the making and recovery of charges for drugs and appliances supplied under the National Health Service Act 1977(2). Provision for dental charges and optical charges is made separately.

<sup>(1)</sup> S.I. 2001/1358 (W.86).

<sup>(</sup>**2**) 1977 c.49.

- **4.** The Regulations provide for exemptions from payment of charges for drugs and appliances which will apply to patients other than those registered with GPs in Wales or registered with GPs in England but holding valid entitlement cards (regulation 8) and further provide for patients registered with GPs in Wales or registered with GPs in England but holding valid entitlement cards to apply for exemption certificates (regulation 9).
- **5.** Regulation 11 provides for the issuing of entitlement cards enabling Welsh residents registered with GPs in England to obtain drugs and appliances free of charge where the same are dispensed by chemists or doctors within Wales.
- **6.** The Regulations also provide for exemption from charges for prisoners (regulation 10).
- **7.** A regulatory appraisal has been prepared in respect of these Regulations and placed in the library of the National Assembly for Wales.

# 2007 No. (W.)

# NATIONAL HEALTH SERVICE, WALES

National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007

Made 2007

Coming into force 1 April 2007

The National Assembly for Wales in exercise of the powers conferred by sections 77, 83, 83A and 126(4) of, and paragraph 1 of Schedule 12 to, the National Health Service Act 1977(1) hereby makes the following Regulations:-

# Title, commencement and application

- 1.—(1) The title of these Regulations is the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 and they come into force on 1 April 2007.
  - (2) These regulations apply in relation to Wales.

# Interpretation

**2.**—(1) In these Regulations, unless the context otherwise requires—

"the Act" ("y Ddeddf") means the National Health Service Act 1977;

"accepted disablement" ("anabledd wedi'i dderbyn") means physical or mental injury or disease which is accepted by the National Assembly as attributable to or aggravated by service in the armed forces of the Crown or such other service as it may determine;

"accredited course" ("cwrs a achredwyd") means a course accredited by the Nursing and Midwifery Council;

(**1**) 1977 c.49.

"appliance" ("cyfarpar") means a listed appliance within the meaning of section 41 of the Act(1);

"batch issue" ("swp-ddyroddiad") means a form provided by a Local Health Board and issued by a repeatable prescriber at the same time as a repeatable prescription to enable a chemist to receive payment for the provision of repeat dispensing services, which is in the format specified in Part 2 of Schedule 1 to the GMS Contract Regulations, and which—

- (a) is generated by a computer and not signed by a repeatable prescriber;
- (b) relates to a particular repeatable prescription and contains the same date as that prescription;
- (c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the repeatable prescription may be provided; and
- (d) specifies a number denoting its place in the sequence referred to in paragraph (c);

"the Charges Regulations 2000" ("Rheoliadau Ffioedd 2000") means the National Health Service (Charges for Drugs and Appliances) Regulations 2000(2):

"the Charges Regulations 2001" ("Rheoliadau Ffioedd 2001") means the National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001(3):

"chemist" ("fferyllydd") includes any person, other than a doctor, providing pharmaceutical services;

"dispensing services" ("gwasanaethau gweinyddu") means services corresponding to pharmaceutical services under the terms of a GMS contract which give effect to paragraphs 47 to 51 of Schedule 6 to the GMS Contract Regulations;

"doctor" ("meddyg") means a registered medical practitioner;

"Drug Tariff" ("Tariff Cyffuriau") means the statement compiled, published and amended from time to time by the National Assembly pursuant to regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992(4) (standards of, and payments for, drugs and appliances):

<sup>(1)</sup> Section 41 of the Act is replaced by section 80 of the National Health Service (Wales) Act 2006 (c.42) with effect from 1 March 2007.

<sup>(2)</sup> S.I. 2000/620, as last amended by S.I. 2006/675.

<sup>(3)</sup> S.I. 2001/1358 (W.86), as last amended by S.I. 2006/1792 (W.188).

<sup>(4)</sup> S.I. 1992/662, as last amended in relation to Wales by S.I. 2005/1013 (W.67).

"drugs" ("cyffuriau") includes medicines;

"elastic hosiery" ("hosan elastig") means anklet, legging, knee-cap, below-knee or thigh stocking;

"entitlement card" ("cerdyn hawl") has the meaning assigned to it by regulation 11(1);

"equivalent batch issue" ("swp-ddyroddiad cyfatebol") means a form provided under equivalent arrangements having effect in England, Scotland and Northern Ireland which is issued by a repeatable prescriber at the same time as an equivalent repeatable prescription to enable a chemist to receive payment for the provision of repeat dispensing services;

"equivalent prescription form" ("ffurflen brescripsiwn gyfatebol") means a form provided and issued under equivalent arrangements having effect in England, Scotland or Northern Ireland to enable a person to obtain pharmaceutical services or local pharmaceutical services, or in Scotland pharmaceutical care services provided under Part 1 of the National Health Service (Scotland) Act 1978(1), and does not include—

- (a) a Welsh prescription form;
- (b) a Welsh repeatable prescription; or
- (c) an equivalent repeatable prescription;

"equivalent repeatable prescription" ("presgripsiwn amlroddadwy cyfatebol") means a prescription contained in a form and issued in accordance with arrangements having effect in England, Scotland and Northern Ireland to enable a person to obtain equivalent repeat dispensing services to those provided within Wales;

"exemption" ("esemptiad") means any exemption provided for in regulation 8;

"exemption certificate" ("tystysgrif esemptio") has the meaning assigned to it by regulation 9(1);

"the GMS Contract Regulations" ("Rheoliadau Contract GMS") means the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(2);

"GMS contract" ("contract GMS") means a general medical services contract under section 28Q of the Act;

"independent nurse prescriber" ("nyrs sy'n rhagnodi'n annibynnol") means a person—

(a) who is registered in the Nursing and Midwifery Register, and

<sup>(</sup>**1**) 1978 c.29.

<sup>(2)</sup> S.I. 2004/478 (W.48) as last amended by S.I. 2006/945 (W.94).

- (b) in respect of whom an annotation signifying that he or she is qualified to order drugs, medicines and appliances from—
  - (i) the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVIIB(i) of the Drug Tariff, or
  - (ii) the Nurse Prescribers' Extended Formulary for Community Practitioners in Part XVIIB(i) of the Drug Tariff,

is also recorded in that register;

"Local Health Board" ("Bwrdd Iechyd Lleol") has the meaning assigned to it by section 16BA of the Act(1);

"National Assembly" ("Cynulliad Cenedlaethol") means the National Assembly for Wales;

"nurse independent prescriber" ("nyrs-ragnodydd annibynnol") means a person—

- (a) whose name is registered in the Nursing and Midwifery Register, and
- (b) who, in respect of a person practising in Wales on or after 1 February 2007, has passed an accredited course to practise as a nurse independent prescriber;

"Nursing and Midwifery Register" ("Cofrestr Nyrsio a Bydwreigiaeth") means the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001(2);

"patient" ("claf") means—

- (a) any person who is provided with primary medical services under Part 1 of the Act(3);
- (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;
- (d) any person who applies to be supplied with a drug in accordance with a Patient Group Direction;

"Patient Group Direction" ("Cyfarwyddyd Grŵp Cleifion") is to be construed in accordance with regulation 7(2);

"pharmacist independent prescriber" ("fferyllydd-ragnodydd annibynnol") means a person—

(c) who is a pharmacist, and

<sup>(1)</sup> Section 16BA of the Act is replaced by section 11 of the National Health Service (Wales) Act 2006 with effect from 1 March 2007.

<sup>(2)</sup> S.I. 2001/253.

<sup>(3)</sup> Primary medical services are provided under Part 4 of the National Health Service (Wales) Act 2006 with effect from 1 March 2007.

(d) against whose name is recorded in the relevant register an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"prescriber" ("rhagnodydd") means—

- (a) a doctor,
- (b) an independent nurse prescriber,
- (c) a supplementary prescriber,
- (d) a nurse independent prescriber, and
- (e) a pharmacist independent prescriber.

"Primary Care Trust" ("Ymddiriedolaeth Gofal Sylfaenol") means a Primary Care Trust established under section 16A of the Act(1);

"prison" ("carchar") includes a young offender institution but not a secure training centre or a naval, military or air force prison, and for the purposes of this definition—

"prisoner" ("carcharor") means a person who is detained in a prison in which medical, dental, ophthalmic, pharmaceutical or nursing services are provided under the Act(2) by, or under arrangements made by a Local Health Board otherwise than by virtue of section 7(2) of the Health and Medicines Act 1988(3) (extension of the powers of Secretary of State for financing the Health Service);

"secure training centre" ("canolfan hyfforddi diogel") means a place in which offenders subject to detention and training orders under section 100 of the Powers of Criminal Courts (Sentencing) Act 2000(4) (offenders under 18: detention and training orders) may be detained and given training and education and prepared for their release; and

"young offender institution" ("sefydliad tramgwyddwyr ifanc") means a place for the detention of offenders sentenced to detention in a young offender institution or to custody for life:

"qualifying patient" ("claf cymwys") has the meaning assigned to it by regulation 11(3);

"relevant register" ("cofrestr berthnasol")
means—

<sup>(1)</sup> Section 16A of the Act is replaced by section 18 of the National Health Service Act 2006 (c.41) with effect from 1 March 2007.

<sup>(2)</sup> Medical, dental, ophthalmic and pharmaceutical services are provided under Parts 4, 5, 6, and 7 of the National Health Service (Wales) Act 2006 respectively with effect from 1 March 2007.

<sup>(</sup>**3**) 1988 c.49.

<sup>(</sup>**4**) 2000 c.6.

- (a) in relation to a nurse or a midwife, the Nursing and Midwifery Register;
- (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954(1) or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(2);
- (c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(3) relating to—
  - (i) chiropodists and podiatrists;
  - (ii) physiotherapists; or
  - (iii) radiographers: diagnostic or therapeutic;

that register; and

(d) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989(4);

"repeat dispensing services" ("gwasanaethau amlweinyddu") means pharmaceutical services which involve the provision of drugs or appliances by a chemist in accordance with a repeatable prescription;

"repeatable prescriber" ("rhagnodydd amlroddadwy") means a prescriber who is—

- (a) a GMS contractor who provides repeatable prescribing services under the terms of its contract which give effect to paragraph 40 of Schedule 6 to the GMS Contract Regulations; or
- (b) employed or engaged by a GMS contractor who provides repeatable prescribing services under the terms of a contract which give effect to paragraph 40 of Schedule 6 to the GMS Contract Regulations;

"supplementary prescriber" ("rhagnodydd atodol") means a person

- (a) whose name is registered in—
  - (i) The Nursing and Midwifery Register,
  - (ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954;

<sup>(</sup>**1**) 1954 c.61.

<sup>(2)</sup> S.R. 1976/1213 (N.I. 22).

<sup>(3)</sup> S.I. 2001/254.

<sup>(</sup>**4**) 1989 c.44.

- (iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976,
- (iv) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—
  - (aa) chiropodists and podiatrists,
  - (bb) physiotherapists,
  - (cc) radiographers: diagnostic or therapeutic, or
- (v) the register of optometrists maintained by the General Optical Council in pursuance of section 7(a) of the Opticians Act 1989, and
- (b) against whose name is recorded in the relevant register an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a supplementary prescriber;

"terms of service" ("telerau gwasanaeth") means the terms on which general ophthalmic services and pharmaceutical services are provided under the Act;

"the Travelling Expenses and Remission of Charges Regulations" ("y Rheoliadau Treuliau Teithio a Pheidio â Chodi Tâl") means the National Health Service (Travelling Expenses and Remission of Charges) Regulations 1988(1);

"treatment" ("triniaeth") includes examination and diagnosis;

"valid entitlement card" ("cerdyn hawl dilys") means an entitlement card which is in force and applies to the patient named on an equivalent prescription form;

"Walk-in centre" ("Canolfan cerdded i mewn") 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 National Assembly;

"Welsh prescription form" ("ffurflen brescripsiwn Gymreig") means a form provided by a Local Health Board or a Welsh NHS Trust and issued by a prescriber or a dentist to enable a person to obtain pharmaceutical services and does not include—

- (a) a Welsh repeatable prescription;
- (b) an equivalent prescription form; or
- (c) an equivalent repeatable prescription,

<sup>(1)</sup> S.I. 1988/551, as last amended by S.I. 2006/2791 (W.232).

and for the purposes of this definition—

"a Welsh NHS Trust" ("un o Ymddiriedolaethau'r GIG yng Nghymru") means an NHS Trust all or most of whose hospitals, establishments and facilities are situated in Wales:

"Welsh repeatable prescription" ("presgripsiwn amolroddadwy Cymreig") means a prescription contained in a form provided by a Local Health Board and issued by a repeatable prescriber to enable a person to obtain pharmaceutical services, which is in the format specified in Part 1 of Schedule 1 to the GMS Contract Regulations and which—

- (a) is generated by a computer but signed by a repeatable prescriber; and
- (b) indicates 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.
- (2) For the purposes of these Regulations the supply against an order on one prescription form, or on one repeatable prescription (but only where the supply is against one batch issue relating to that repeatable prescription)—
  - (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.
- (3) For as long as there are in existence contracts entered into under article 13 of the General Medical Services Transitional and Consequential Provisions (Wales) Order 2004(1) ("default contracts") any reference in these Regulations to a GMS contract shall be read as including a reference to a contract entered into under that article and any reference to a term of a GMS contract shall be read as including a reference to the equivalent term of the default contract.
- (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

<sup>(</sup>**1**) S.I. 2004/477 (W.47).

- **3.**—(1) A chemist who provides pharmaceutical services to a patient must not make or recover a charge for any drugs or appliances supplied as part of those services in the following circumstances—
  - (a) where the patient presents a Welsh prescription form; or
  - (b) where the patient presents both an equivalent prescription form and a valid entitlement card.
- (2) Save where the circumstances in paragraph (1) (a) and (b) above are satisfied, a chemist who provides pharmaceutical services to a patient, must, subject to paragraph (6), make and recover from that patient,—
  - (a) in respect of an item of elastic hosiery the charge that is specified in regulation 3(1)(a) of the Charges Regulations 2000,
  - (b) in respect of the supply of each other appliance and each quantity of a drug, the charge that is specified in regulation 3(1)(b) of the Charges Regulations 2000.
- (3) Where a charge is paid under paragraph (2), the person making the payment must on doing so sign a declaration in writing on the equivalent prescription form that the relevant charge has been paid.
- (4) A chemist who provides repeat dispensing services to a patient must not make or recover a charge for any drugs or appliances supplied as part of those services in the following circumstances—
  - (a) where a batch issue applies to the supply of any appliance or quantity of drug dispensed by the chemist to that patient; or
  - (b) where an equivalent batch issue applies to the supply of any appliance or quantity of drug dispensed by the chemist to that patient and where the patient presents a valid entitlement card.
- (5) Save where the circumstances in paragraph (4) (a) and (b) above are satisfied, a chemist who provides repeat dispensing services to a patient must, subject to paragraph (6), make and recover from that patient—
  - (a) in respect of an item of elastic hosiery, the charge specified in regulation 3(1A)(b)(i) of the Charges Regulations 2000,
  - (b) in respect of the supply of each other appliance and of each quantity of a drug, the charge that is specified in regulation 3(1A)(b)(ii) of the Charges Regulations 2000.
- (6) Where a charge is paid under paragraph (5), the person making the payment must on doing so sign a declaration in writing on the equivalent batch issue that the relevant charge has been paid.
- (7) For the purposes of paragraph (2) where a drug ordered on a single equivalent prescription is supplied

by instalments, the charge specified in regulation 3(4) of the Charges Regulations 2000 must be paid upon the supply of the first instalment.

- (8) No charges may be made and recovered under paragraphs (2) or (5) where—
  - (a) there is an exemption under regulation 8 and a declaration of entitlement to exemption is duly completed by or on behalf of the patient—
    - (i) in cases where an equivalent prescription form is presented, on the equivalent prescription form,
    - (ii) in cases falling within paragraph (5) on the equivalent batch issue relating to the equivalent repeatable prescription, at the time the drug or appliance is supplied;
  - (b) the patient is resident in a school or institution the name of which is inserted on the equivalent prescription form by a prescriber pursuant to the term of a GMS Contract which gives effect to paragraph 44(2) of Schedule 6 to the GMS Contract Regulations or of other arrangements for the provision of primary medical services made under section 16CC(2) of the Act(1);
  - (c) 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 is duly completed by or on behalf of the patient in accordance with regulation 7 of those Regulations.
- (9) A chemist, notwithstanding his or her terms of service, is under no obligation to provide pharmaceutical services in respect of an order on—
  - (a) an equivalent prescription form,
  - (b) an equivalent repeatable prescription,

unless he or she is first paid by the patient any charge required to be made and recovered by paragraph (2) or (5), as the case may be, in respect of that order.

(10) A chemist who makes and recovers a charge under paragraph (2) or (5) must, if so required by the patient, give the patient a receipt for the amount received on the form provided for the purpose which form must contain forms of declaration in support of an application for repayment and information as to whom an application for repayment should be made.

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<sup>(1)</sup> Section 16CC(2) of the Act is replaced by section 41(2) of the National Health Service (Wales) Act 2006 with effect from 1 March 2007.

(11) Any sum which would otherwise be payable by a Local Health Board to a chemist in respect of the provision by the chemist of pharmaceutical services will 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 must not make or recover a charge for any drugs or appliances supplied as part of those services in the following circumstances—
  - (a) where the patient presents a Welsh prescription form; or
  - (b) where the patient presents both an equivalent prescription form and a valid entitlement card.
- (2) Save where the circumstances in paragraph (1)(a) and (b) above are satisfied, a doctor who provides pharmaceutical services to a patient, must, subject to paragraph (3), make and recover from that patient,—
  - (a) in respect of an item of elastic hosiery the charge that is specified in regulation 4(1)(a) of the Charges Regulations 2000,
  - (b) in respect of the supply of each other appliance and each quantity of a drug, the charge that is specified in regulation 4(1)(b) of the Charges Regulations 2000.
- (3) No charge may be made and recovered under paragraph (2) where—
  - (a) there is exemption under regulation 8 and a declaration of entitlement to exemption on the equivalent prescription form is duly completed by or on behalf of the patient; or
  - (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 is duly completed by or on behalf of the patient in accordance with regulation 7 of those Regulations.
- (4) Where a charge is paid under paragraph (2), the person making the payment must on doing so sign a declaration in writing on the equivalent prescription form that the relevant charge has been paid.
- (5) For the purposes of this paragraph (2) where a drug ordered on a single equivalent prescription form is supplied by instalments, the charge specified in regulation 4(4) of the Charges Regulations 2000 payable for that drug must be paid upon the supply of the first instalment.
- (6) A doctor is under no obligation to provide pharmaceutical services for which a charge is required

to be made and recovered by paragraph (2) unless he or she is first paid the amount of that charge by the patient.

- (7) A doctor who makes and recovers a charge under paragraph (2) must, if so required by the patient, give the patient a receipt for the amount received on the form provided for the purpose which form must contain forms of declaration in support of an application for repayment and information as to whom an application for repayment should be made.
- (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 an equivalent prescription form; or
  - (b) is administered or applied to the patient by the doctor personally.

# Supply of drugs and appliances by Local Health Boards and NHS trusts

**5.** A patient is not liable to pay charges to a Local Health Board or an NHS trust which supplies to that patient for the purposes of his or her treatment, drugs, or appliances.

# Supply of drugs and appliances at Walk-in centres

**6.** A patient is not liable to pay charges for drugs or appliances supplied for the purposes of his or her treatment by a prescriber at a Walk-in Centre or for drugs administered or appliance fitted at the Centre.

#### **Supply of drugs under Patient Group Directions**

- 7.—(1) A patient is not liable to pay charges for drugs supplied in accordance with a Patient Group Direction or for drugs supplied for personal administration by any person making the supply in accordance with the Patient Group Direction.
- (2) For the purposes of this regulation the reference to the supply of a drug in accordance with a Patient Group Direction is a reference to the supply of a drug for that purpose as provided for in the Medicines (Pharmacy and General Sale Exemption) Order 1980(1) or in the Prescription Only Medicines (Human Use) Order 1997(2).

<sup>(</sup>**1**) S.I. 1980/1924.

<sup>(</sup>**2**) S.I. 1997/1830.

# **Exemptions**

- **8.**—(1) Subject to paragraph (3), no charge will be payable under paragraphs (2) or (5) of regulation 3 or paragraph (2) of regulation 4 by
  - (a) a person who is exempt under paragraph 1(1)(a) to (d) of Schedule 12 to the Act(1);
  - (b) a person who has attained the age of 60 years;
  - (c) a woman with a valid exemption certificate issued by arrangements in England, Scotland or Northern Ireland 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(2);
  - (d) a person with a valid exemption certificate issued under arrangements for exemptions from charges for drugs and appliances in England, Scotland or Northern Ireland on the ground that he or she is suffering from one of 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 anticonvulsive therapy;
- (iv) a continuing physical disability which prevents the patient from leaving his or her residence without the help of another person:
- (e) a person with a valid exemption certificate issued under arrangements for exemptions from charges for drugs and appliances in England, Scotland or Northern Ireland in

<sup>(1)</sup> Sub-paragraphs (1)(a) to (d) of paragraph 1 of Schedule 12 to the Act is replaced by sub-paragraphs (1)(a) to (d) respectively of section 122 of the National Health Service (Wales) Act 2006 with effect from 1 March 2006.

<sup>(</sup>**2**) 1953 c.20.

- respect of the supply of drugs and appliances for the treatment of accepted disablement;
- (f) a person with a valid pre-payment certificate issued under arrangements for exemptions from charges for drugs and appliances in England, Scotland or Northern Ireland.
- (2) Subject to paragraph (3) a person who wishes to claim entitlement to exemption under paragraph (1) must provide any declaration of entitlement required under regulations 3(8) or 4(3).
- (3) A person who is exempt under paragraph 1(1)(c) of Schedule 12 to the Act or under paragraph (1)(b) of this regulation is not required to provide any declaration of entitlement required by regulations 3(8) or 4(3) where—
  - (a) an equivalent prescription form; or
  - (b) an equivalent repeatable prescription,
  - is issued and the person's date of birth is printed by means of a computer on the relevant form.
- (4) An exemption by reference to age or the validity of an exemption certificate is to 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.
- (5) 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 Local Health Board or, where the drugs or appliances were supplied by an NHS trust, that NHS trust must recover such charge from the person concerned.

### Certificates of exemption – application and issue

- **9.**—(1) Notwithstanding the provisions of regulations 3(1) and (4), 4(1), 5, 6 and 7(1), a person who wishes to claim exemption on the ground that
  - (a) 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;
  - (b) he or she is suffering from one or more of the conditions set out in paragraph (i) to (iv) of regulation 8(1)(d);
  - (c) he or she requires the supply of drugs and/or appliances for the treatment of accepted disablement

may apply for a certificate conferring exemption (to be known as an "exemption certificate") to the Local Health Board in the case of an exemption under sub-paragraph (a) or (b) on a form supplied

for that purpose and in the case of an exemption under sub-paragraph (c) to an office of the Department of Social Security on a form supplied for that purpose by the National Assembly.

- (2) A Local Health Board, on being satisfied that an applicant is entitled to exemption under paragraph (1)(a), must issue an exemption certificate which will 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 Local Health Board, on being satisfied that an applicant is entitled to exemption under paragraph (1)(b) must issue to the applicant an exemption certificate which will be valid for such period as it may determine.
- (4) The National Assembly, on being satisfied that an applicant is entitled to exemption under paragraph (1)(c), will issue to the applicant an exemption certificate which will be valid for such period as it may determine.

# **Exemption from charges for prisoners**

**10.** A prisoner is not liable to pay any charges under these Regulations.

#### **Entitlement cards**

- 11.—(1) A Local Health Board, on being satisfied that a person is a qualifying patient, must issue to that person a card (in these Regulations referred to as an "entitlement card") which will be valid for such period as the Local Health Board may determine.
- (2) An entitlement card which is issued confers on the qualifying patient the right to obtain drugs and appliances free of charge under paragraphs (1)(b) and (4)(b)(i) of regulation 3 and paragraph 1(b) of regulation 4;
- (3) For the purposes of these Regulations "a qualifying patient" means a person who—
  - (a) is resident in Wales; and
  - (b) receives primary medical services under Part 1 of the Act from a provider who is contracted

to provide such services with a Primary Care Trust; and

includes a person acting on behalf of such a person.

# **Transitional Provisions**

**12.** The transitional provisions in Schedule 1 take effect.

# **Minor and Consequential Amendments**

**13.** The provisions listed in Schedule 2 are amended as therein specified.

# Revocations

**14.** The Regulations specified in column (1) of Schedule 3 are revoked in relation to Wales to the extent specified in column (3) of that Schedule.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(1).

Date

The Presiding Officer of the National Assembly.

<sup>(</sup>**1**) 1998 c.38.

# SCHEDULE 1

# **Transitional Provisions**

Regulation 12

# Repayment of charges

- 1.—(1) Where a charge has been paid under the Charges Regulations 2001 by or on behalf of a person who was at the time of payment exempt from the requirement to pay that charge under regulation 8 of those Regulations, 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 must
    - (a) be made to the person or body specified in the receipt which is given under regulation 3(8), 4(6), 5(6), 6(5) or 7(5) of the Charges Regulations 2001 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 National Assembly 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 the National Assembly 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 to the Charges Regulations 2001, regulation 11(3) of the Charges Regulations 2001 applies.
- (4) Arrangements made by the National Assembly for the repayment of any charge paid under regulation 11(4) of the Charges Regulations 2001 by a person who is entitled to exemption continue to have effect for the purposes of paragraph 1.

#### **Pre payment Certificates**

2.—(1) Where a person has obtained a pre-payment certificate by virtue of making any payment in accordance with regulation 10 of the Charges Regulations 2001, and the relevant period as defined

by paragraph (3) is unexpired, an application for a refund may be made, by or on behalf of that person or his or her estate, in accordance with paragraph (4) in respect of each complete month following 1 April 2007.

- (2) The refund referred to in paragraph (1) is calculable as follows—
  - (a) in the case of a pre-payment certificate valid for 4 months, one quarter of the prescribed sum paid for each complete month during which the pre-payment certificate is or was valid:
  - (b) in the case of a pre-payment certificate valid for 12 months one twelfth of the prescribed sum paid for each complete month during which the pre-payment certificate is or was valid:

and for the purposes of these calculations "complete month" means a month beginning on the monthly anniversary of the date upon which the pre-payment certificate became valid and ending on the date immediately preceding that date in the following month.

- (3) In paragraph (1) "the relevant period" means the period of validity of the pre-payment certificate excluding the month in respect of which an application for repayment under paragraph (1) may be made.
- (4) Applications under this regulation must be made to the Local Health Board that received the prescribed sum under regulation 10 of the Charges Regulations 2001 and must be accompanied by the certificate (where granted) and a declaration in support of the claim, and the claim and any repayment must be made in such manner and subject to such conditions as the National Assembly may determine.

# SCHEDULE 2

# Minor and Consequential Amendments

Regulation 13

# The National Health Service (Pharmaceutical Services) Regulations 1992

- **1.**—(1) The National Health Service (Pharmaceutical Services) Regulations 1992 are amended as provided in this paragraph.
- (2) In regulation 2(1) (interpretation) substitute the definition of "the Charges Regulations" with the following—  $\,$ 
  - ""the Charges Regulations" means the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007".
- (3) In paragraph (7) of Part 2 (Essential Services) of Schedule 2 delete the term "or (1A)".

# The National Health Service (Travelling Expenses and Remission of Charges) (Wales) Regulations 1988

- **2.** Substitute the entirety of paragraph (1)(b) of regulation 7 of the National Health Service (Travelling Expenses and Remission of Charges) (Wales) Regulations 1988 with the following—
  - "(1)(b) provide any declaration of entitlement required under regulation 3(8) or 4(3) of the National Health Services (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007."

# The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004.

- **3.**—(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 are amended as provided in this paragraph.
- (2) In paragraph 11A of Part 1 of Schedule 6 (Other Contractual Terms)—
  - (a) in sub-paragraph (1) substitute the definition of "the Charges Regulations" with the following—
  - ""the Charges Regulations" means the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007".
  - (b) in sub-paragraph (5)(a)substitute the term "4(1)" with the term "4(3)".

# SCHEDULE 3.

# REGULATIONS REVOKED

Regulation 14

Regulation

(1) (2) (3)

Extent Regulations revoked Reference of revocation

National Health Service SI 2001/1358 The whole Regulations (Charges for Drugs and (W.86) except Appliances) (Wales) regulation Regulations 2001

11(3) and

(4).

11(3) and 11(4) with effect from 1 July 2007.

National Health Service SI 2001/1359 The whole Regulations (Charges for Drugs and (W.196)

Appliances)

(Amendment) (Wales)

Regulations 2001

National Health Service SI 2003/2624 Regulation

(Amendments (W.252)

concerning

Supplementary and Independent Nurse Prescribing) (Wales)

Regulations 2003

National Health Service SI 2004/1018 Regulations

1(4), 7 and (Pharmaceutical (W.115)

Services 8 etc)

(Repeatable

Prescriptions)

(Amendment) (Wales)

Regulations 2004

National Health Service SI 2004/1605 The whole (Charges for Drugs and (W.164) Regulations

Appliances) (Wales)

(Amendment)

Regulations 2004

1999 SI 2004/1771 Paragraph Health Act

29 of Part 2 (Consequential

Amendments) (Nursing of Schedule and Midwifery) Order 2 2004

General Medical SI 2004/1016 Paragraph
Services Transitional (W.113) 24 of
and Consequential Schedule 1
Provisions (Wales)
(No.2) Order 2004

National Health Service SI 2005/427 The whole (Charges for Drugs and (W.44) Regulations Appliances) (Wales) (Amendment)
Regulations 2005

National Health Service SI 2005/1915 The whole (Charges for Drugs and (W.158) Regulations Appliances) (Wales) (Amendment) (No.2) Regulations 2005

National Health Service SI 2006/943 The whole (Charges for Drugs and (W.92) Regulations Appliances) (Wales) (Amendment) Regulations 2006

General Dental Services SI 2006/946 Paragraph 4 and Personal Dental (W.95) of Schedule Services Transitional and 1 Consequential Provisions (Wales) Order 2006

National Health Service SI 2006/1792 The whole (Charges for Drugs and (W.188) Regulations Appliances) (Wales) (Amendment) (No.2) Regulations 2006