#### WELSH STATUTORY INSTRUMENTS

# 2007 No. 121 (W.11)

# NATIONAL HEALTH SERVICE, WALES

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

 Made
 23 January 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.

# Commencement Information I1 Reg. 1 in force at 1.4.2007, see reg. 1(1)

# Interpretation

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

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

[F1"the 2006 Act" ("Deddf 2006") means the National Health Service (Wales) Act 2006(3);]

"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;

<sup>(1) 1977</sup> c. 49

<sup>(3)</sup> S.I.2000/620, as last amended by S.I. 2006/675.

Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

"appliance" ("cyfarpar") means a listed appliance within the meaning of section 41 of the Act(2);

"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(3);

"the Charges Regulations 2001" ("Rheoliadau Ffioedd 2001") means the National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001(4);

"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;

[F2": Drug Tariff ("Tariff Cyffuriau") means the aggregate of the determinations made by the National Assembly for Wales which are published in accordance with regulation 18(e) of the National Health Service (Pharmaceutical Services) Regulations 1992 (provisions relating to determinations);]

"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(5), and does not include—

- (a) a Welsh prescription form;
- (b) a Welsh repeatable prescription; or

<sup>(2)</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>(3)</sup> S.I.2000/620, as last amended by S.I. 2006/675.

<sup>(4)</sup> S.I. 2001/1358 (W.86), as last amended by S.I. 2006/1792 (W.188).

<sup>(</sup>**5**) 1978 c. 29.

Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

(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(6);

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

[F3. independent nurse prescriber" ("nyrs sy'n rhagnodi'n annibynnol") means a person —

- (a) who is registered in the Nursing and Midwifery Register, and
- (b) against whose name in that register is recorded an annotation or entry signifying that he or she is qualified to order drugs, medicines and appliances as a community practitioner nurse prescriber;

[F4"independent nurse prescriber" ("nyrs sy'n rhagnodi'n annibynnol") means a person —

- (a) who is registered in the Nursing and Midwifery Register, and
- (b) against whose name in that register is recorded an annotation or entry signifying that he or she is qualified to order drugs, medicines and appliances as a community practitioner nurse prescriber;]

"Local Health Board" ("Bwrdd Iechyd Lleol") has the meaning assigned to it by section 16BA of the Act(7);

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

"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(8);

"patient" ("claf") means—

- (a) any person who is provided with primary medical services under Part 1 of the Act(9);
- (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 Grwp 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>(6)</sup> S.I. 2004/478 (W.48) as last amended by S.I. 2006/945 (W.94).

<sup>(7)</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>(8)</sup> S.I. 2001/253.

<sup>(9)</sup> Primary medical services are provided under Part 4 of the National Health Service (Wales) Act 2006 with effect from 1 March 2007.

Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

(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(10);

"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(11) 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(12) (extension of the powers of Secretary of State for financing the Health Service);

[F5"the POM Order" ("y Gorchymyn MBU") means the Prescription Only Medicines (Human Use) Order 1997(8);

"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(13) (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—

- (a) in relation to a nurse or a midwife, the Nursing and Midwifery Register;
- (b) [F6in relation to a pharmacist, the register maintained under article 19 of the Pharmacy Order 2010 or the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976.]
- (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 [F7Health and Social Work Professions Order 2001] relating to—
  - (i) chiropodists and podiatrists;
  - (ii) physiotherapists; or
  - (iii) radiographers: diagnostic or therapeutic;

that register; and

 $<sup>\</sup>textbf{(10)} \ \ Section \ 16 A \ of the \ Act \ is \ replaced \ by \ section \ 18 \ of the \ National \ Health \ Service \ Act \ 2006 \ (c.\ 41) \ with \ effect \ from \ 1 \ March \ 2007.$ 

<sup>(11)</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>(12) 1988</sup> c. 49.

<sup>(8)</sup> S.I. 2001/253.

<sup>(13) 2000</sup> c. 6.

Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

(d) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989(14);

"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) [F8Part 1 of the register maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007;]
  - (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 [F9Health and Social Work 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 [F10, save in the case of the Nursing and Midwifery Register, where the annotation or entry signifies qualification as a nurse independent/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(15);

"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;

<sup>(14) 1989</sup> c. 44.

<sup>(15)</sup> S.I. 1988/551, as last amended by S.I. 2006/2791 (W.232).

"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,

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.
- [FII(2A)] Where the term "community practitioner nurse prescriber" appears in the POM Order or the Nursing and Midwifery Register it is to be construed for the purposes of these Regulations as a reference to an "independent nurse prescriber".]
- (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(16) ("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.

#### **Textual Amendments**

- F1 Words in reg. 2 inserted (20.10.2009) by The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2009 (S.I. 2009/2607), regs. 1(1), 2
- **F2** Words in reg. 2(1) substituted (1.4.2007) by The National Health Service (Pharmaceutical Services) (Remuneration for Persons providing Pharmaceutical Services) (Amendment) (Wales) Regulations 2007 (S.I. 2007/1112), regs. 1(2), **11**

(16) S.I. 2004/477 (W.47).

Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

- F3 Words in reg. 2(1) substituted (19.7.2010) by The National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) (Wales) Regulations 2010 (S.I. 2010/1647), regs. 1(1), 4(2)(a) (with reg. 5)
- F4 Words in reg. 2(1) substituted (19.7.2010) by The National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) (Wales) Regulations 2010 (S.I. 2010/1647), regs. 1(1), 4(2)(b) (with reg. 5)
- Words in reg. 2(1) inserted (19.7.2010) by The National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) (Wales) Regulations 2010 (S.I. 2010/1647), regs. 1(1), 4(2)(e) (with reg. 5)
- **F6** Words in reg. 2(1) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch.** 4 para. 55 (with Sch. 5); S.I. 2010/1621, art. 2(1), Sch.
- Words in reg. 2(1) substituted (1.8.2012) by The Health and Social Care Act 2012 (Consequential Provision—Social Workers) Order 2012 (S.I. 2012/1479), art. 1(2), Sch. para. 50(2)(a)
- F8 Words in reg. 2(1) substituted (19.7.2010) by The National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) (Wales) Regulations 2010 (S.I. 2010/1647), regs. 1(1), 4(2)(d)(i) (with reg. 5)
- **F9** Words in reg. 2(1) substituted (1.8.2012) by The Health and Social Care Act 2012 (Consequential Provision—Social Workers) Order 2012 (S.I. 2012/1479), art. 1(2), **Sch. para. 50(2)(b)**
- Words in reg. 2(1) inserted (19.7.2010) by The National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) (Wales) Regulations 2010 (S.I. 2010/1647), regs. 1(1), 4(2)(d)(ii) (with reg. 5)
- F11 Reg. 2(2A) inserted (19.7.2010) by The National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) (Wales) Regulations 2010 (S.I. 2010/1647), regs. 1(1), 4(3) (with reg. 5)

#### **Commencement Information**

**I2** Reg. 2 in force at 1.4.2007, see reg. 1(1)

# Supply of drugs and appliances by chemists

- **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) or (b) above are satisfied, a chemist 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 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) or (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 form 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(17);
    - (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.

- [F12(10)] A chemist who makes and recovers a charge—
  - (a) under paragraph (2) from or on behalf of a patient who is a person described in regulation 11A(1) must, if so required by the patient or the patient's representative, provide a receipt for the amount received in the form approved by the Welsh Ministers;
  - (b) under paragraph (2) or (5) from or on behalf of a patient who is not a person described in regulation 11A (1) must, if so required by the patient or the patient's representative, provide a receipt for the amount received on the form provided for the purpose, which

<sup>(17)</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.

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.]

(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.

#### **Textual Amendments**

F12 Reg. 3(10) substituted (20.10.2009) by The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2009 (S.I. 2009/2607), regs. 1(1), 3(2)

#### **Commencement Information**

**I3** Reg. 3 in force at 1.4.2007, see **reg. 1(1)** 

#### 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 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.
  - [F13(7)] A doctor who makes and recovers a charge under paragraph (2)—

- (a) from or on behalf of a patient who is a person described in regulation 11A(1) must, if so required by the patient or the patient's representative, provide a receipt for the amount received in the form approved by the Welsh Ministers;
- (b) from or on behalf of a patient who is not a person described in regulation 11A(1) must, if so required by the patient or the patient's representative, provide 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.

#### **Textual Amendments**

F13 Reg. 4(7) substituted (20.10.2009) by The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2009 (S.I. 2009/2607), regs. 1(1), 4(2)

#### **Commencement Information**

**I4** Reg. 4 in force at 1.4.2007, see **reg. 1(1)** 

## 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.

#### **Commencement Information**

**I5** Reg. 5 in force at 1.4.2007, see **reg. 1(1)** 

#### 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.

#### **Commencement Information**

**I6** Reg. 6 in force at 1.4.2007, see reg. 1(1)

#### **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

Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

Medicines (Pharmacy and General Sale — Exemption) Order 1980(18) or in the Prescription Only Medicines (Human Use) Order 1997(19).

#### **Commencement Information**

I7 Reg. 7 in force at 1.4.2007, see reg. 1(1)

[F147A. (Supply of drugs in the event of a pandemic)

- (1) No charges may be made or recovered under these Regulations in respect of a supply of drugs which is—
  - (a) made—
    - (i) while a disease is pandemic, or
    - (ii) in anticipation of a disease being imminently pandemic,

and is a serious risk, or potentially a serious risk, to human health; and

(b) in accordance with a protocol relating to that disease as provided for in article 12F of the Prescription Only Medicines (Human Use) Order 1997(3) or article 8 of the Medicines (Pharmacy and General Sale-Exemption) Order 1980(4).]

#### **Textual Amendments**

F14 Reg. 7A inserted (8.5.2009) by The National Health Service (Charges) (Amendments Relating to Pandemic Influenza) (Wales) Regulations 2009 (S.I. 2009/1175), regs. 1(1), 2(2)

# **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(20);
  - (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(21);
  - (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

<sup>(18)</sup> S.I. 1980/1924.

<sup>(19)</sup> S.I. 1997/1830.

 $<sup>\</sup>begin{tabular}{ll} \textbf{(3)} & S.I.2000/620, as last amended by S.I. $2006/675$. \end{tabular}$ 

<sup>(4)</sup> S.I. 2001/1358 (W.86), as last amended by S.I. 2006/1792 (W.188).

<sup>(20)</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>(21) 1953</sup> c. 20.

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 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 respect of the supply of drugs and appliances for the treatment of accepted disablement;
- [F15(ea) a person with a valid exemption certificate issued by a Local Health Board on the ground that the person is undergoing treatment for—
  - (i) cancer;
  - (ii) the effects of cancer, or
  - (iii) the effects of cancer treatment,

where the certificate is used in respect of drugs or appliances which are supplied on or after 1 November 2009.

- (eb) a person with a valid exemption certificate issued on any of the grounds in subparagraph (ea) under equivalent arrangements which have effect in England, Scotland or Northern Ireland where the certificate is used in respect of drugs or appliances which are supplied on or after 1 November 2009.]
  - (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.

#### **Textual Amendments**

F15 Reg. 8(1)(ea)(eb) inserted (20.10.2009) by The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2009 (S.I. 2009/2607), regs. 1(1), 5

#### **Commencement Information**

**I8** Reg. 8 in force at 1.4.2007, see reg. 1(1)

#### 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[F16];
- (d) he or she is a person undergoing treatment as specified in regulation 8(1)(ea)] 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 [F17, substitute "under sub-paragraph (a), (b) or (d)] 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 [F18 under paragraph (1)(b) or (1)(d)] 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.

#### **Textual Amendments**

- F16 Reg. 9(1)(d) and semi colon inserted (20.10.2009) by The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2009 (S.I. 2009/2607), regs. 1(1), 6(2)(a)
- F17 Words in reg. 9(1) substituted (20.10.2009) by The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2009 (S.I. 2009/2607), regs. 1(1), 6(2)(b)

Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

**F18** Words in reg. 9(3) substituted (20.10.2009) by The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2009 (S.I. 2009/2607), regs. 1(1), **6(3)** 

#### **Commencement Information**

**19** Reg. 9 in force at 1.4.2007, see **reg. 1(1)** 

#### **Exemption from charges for prisoners**

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

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Commencement Information
I10 Reg. 10 in force at 1.4.2007, see reg. 1(1)
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#### **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.

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Commencement Information
111 Reg. 11 in force at 1.4.2007, see reg. 1(1)
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# [F19Repayment of certain charges paid under the Charges Regulations 2000

- 11A.—(1) Where a charge has been paid under the Charges Regulations 2000, whether or not in accordance with these Regulations, by or on behalf of a person who is, at the time the charge was paid, a person who—
  - (a) is resident in Wales; and
  - (b) receives primary medical services under Part 4 of the 2006 Act from a provider who is contracted to provide such services with a Local Health Board,

an application for the repayment of that charge may be made in accordance with paragraph (2).

- (2) An application for repayment made by or on behalf of a person described in paragraph (1) must—
  - (a) be made in such form and manner as the Welsh Ministers may determine;
  - (b) be made within 3 months from the date on which the charge was paid, or within such period as the Welsh Ministers may, for good cause, allow; and

Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

(c) be accompanied by the receipt for the charge paid and a declaration that the person was, at the time the charge was paid, a person described in paragraph (1).]

#### **Textual Amendments**

**F19** Reg. 11A inserted (20.10.2009) by The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2009 (S.I. 2009/2607), regs. 1(1), **7(1)** 

#### **Transitional Provisions**

12. The transitional provisions in Schedule 1 take effect.

#### **Commencement Information**

I12 Reg. 12 in force at 1.4.2007, see reg. 1(1)

## **Minor and Consequential Amendments**

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

#### **Commencement Information**

**I13** Reg. 13 in force at 1.4.2007, see **reg. 1(1)** 

# 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.

# **Commencement Information**

**I14** Reg. 14 in force at 1.4.2007, see reg. 1(1)

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(22)

23 January 2007

D. Elis-Thomas
The Presiding Officer of the National Assembly

#### SCHEDULE 1

Regulation 12

#### **Transitional Provisions**

#### 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.

# Commencement Information I15 Sch. 1 para. 1 in force at 1.4.2007, see reg. 1(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.

Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

- (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.

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Commencement Information
I16 Sch. 1 para. 2 in force at 1.4.2007, see reg. 1(1)
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#### SCHEDULE 2

Regulation 13

#### Minor and Consequential Amendments

### 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)".

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Commencement Information

I17 Sch. 2 para. 1 in force at 1.4.2007, see reg. 1(1)
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# 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—
  - (b) "(1) 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."

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Commencement Information
118 Sch. 2 para. 2 in force at 1.4.2007, see reg. 1(1)
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Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

# 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)".

#### **Commencement Information**

Sch. 2 para. 3 in force at 1.4.2007, see reg. 1(1)

#### **SCHEDULE 3**

Regulation 14

#### REGULATIONS REVOKED

# **Commencement Information** Sch. 3 in force at 1.4.2007, see reg. 1(1)

(1)	(2)	(3)
Regulations revoked	Reference	Extent of revocation
National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001	SI 2001/1358 (W.86)	The whole Regulations except regulation 11(3) and (4).Regulation 11(3) and 11(4) with effect from 1 July 2007.
National Health Service (Charges for Drugs and Appliances) (Amendment) (Wales) Regulations 2001	SI 2001/1359 (W.196)	The whole Regulations
National Health Service (Amendments concerning Supplementary and Independent Nurse Prescribing) (Wales) Regulations 2003	SI 2003/2624 (W.252)	Regulation 4
National Health Service (Pharmaceutical Services etc) (Repeatable Prescriptions) (Amendment) (Wales) Regulations 2004	SI 2004/1018 (W.115)	Regulations 1(4), 7 and 8
National Health Service (Charges for Drugs and	SI 2004/1605 (W.164)	The whole Regulations
	18	

Changes to legislation: There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007. (See end of Document for details)

<u>(1)</u>	(2)	(3)
Regulations revoked	Reference	Extent of revocation
Appliances) (Wales) (Amendment) Regulations 2004		
Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004	SI 2004/1771	Paragraph 29 of Part 2 of Schedule 2
General Medical Services Transitional and Consequential Provisions (Wales) (No.2) Order 2004	SI 2004/1016 (W.113)	Paragraph 24 of Schedule 1
National Health Service (Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2005	SI 2005/427 (W.44)	The whole Regulations
National Health Service (Charges for Drugs and Appliances) (Wales) (Amendment) (No.2) Regulations 2005	SI 2005/1915 (W.158)	The whole Regulations
National Health Service (Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2006	SI 2006/943 (W.92)	The whole Regulations
General Dental Services and Personal Dental Services Transitional and Consequential Provisions (Wales) Order 2006	SI 2006/946 (W.95)	Paragraph 4 of Schedule 1
National Health Service (Charges for Drugs and Appliances) (Wales) (Amendment) (No.2) Regulations 2006	SI 2006/1792 (W.188)	The whole Regulations

#### **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(23) 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(24). Provision for dental charges and optical charges is made separately.
- **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.

<sup>(23)</sup> S.I. 2001/1358 (W.86).

<sup>(24) 1977</sup> c. 49.

# **Status:**

Point in time view as at 01/08/2012.

# **Changes to legislation:**

There are currently no known outstanding effects for the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007.