2011 No. 47

THE NATIONAL HEALTH SERVICE (WALES) ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2011

Made - - - -	*31 October 2011*
Coming into force - -	*1 November 2011*

The Welsh Ministers, in exercise of the powers conferred on them by sections 12(3), 81, 82, 203(9) and (10) and 204(1) of the National Health Service (Wales) Act 2006(**1**), herby give the following Directions—

Title, commencement, application and interpretation

1.—(1) The title of these Directions is the Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2011.

(2) These Directions come into force on 1 November 2011.

(3) These Directions are given to Local Health Boards and apply in relation to Wales.

(4) In these Directions "the principal Directions" means the Pharmaceutical Services (Advanced and Enhanced Services) (Wales) Directions 2005(**2**).

Amendment of Direction 2 of the principal Directions

2. In Direction 2 (interpretation) of the principal Directions insert the following definitions in the appropriate place in the alphabetical order —

""BNF" means the British National Formulary No.62 published September 2011(**3**);",

""high risk medicine" has the meaning given in paragraph 1 and 2 of Schedule B;", and

""NHS Wales Shared Services Partnership" means the NHS bodies that are the parties to the arrangements made pursuant to the NHS Wales Shared Services Directions 2011(**4**);".

Amendment of Direction 3 of the principal Directions

3.—(1) Direction 3 (Advanced Services: Medicines Use Review and Prescription Intervention Service) of the principal Directions is amended as follows.

(2) In paragraph (6) after the words "pursuant to paragraph (1) provide" insert the word "that".

(3) For sub-paragraph (f) of paragraph (6) substitute the following —

(**1**) 2006 c.42.

(**2**) The Pharmaceutical Services (Advanced and Enhanced Services) (Wales) Directions 2005 have been amended by the Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2006 (2006 No.88) and the Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2008 (2008 No.11).

(**3**) The British National Formulary is one of the specified publications mentioned in section 103(1) of the Medicines Act 1968 (c.67). The Formulary is available at www.bnf.org.

(**4**) 2011 No.13.

"(f) a patient must not have —

(i) more than one MUR service consultation in any period of 12 months unless in the reasonable opinion of a registered pharmacist the patient's circumstances have changed sufficiently to justify one or more further consultations during this period, or

(ii) an MUR service consultation within 6 months of a consultation as part of a Discharge Medicines Review Service, unless in the reasonable opinion of a registered pharmacist there are significant potential benefits to the patient which justify providing MUR services to them during this period;".

(4) In sub-paragraph (j) of paragraph (6) after the semicolon omit the word "and".

(5) In sub-paragraph (k) of paragraph (6) for the full stop at the end of the sub-paragraph substitute "; and".

(6) After sub-paragraph (k) of paragraph (6) insert the following —

"(l) subject to paragraph (7), at least 50% of the MUR services consultations carried out by the chemist at or from a pharmacy in any financial year are to be carried out with patients who are in one or more of the national target groups set out in Schedule B;

(m) the chemist provides information from the record mentioned in sub-paragraph (h) to the Local Health Board or the NHS Wales Shared Services Partnership on request, in the manner approved for this purpose, and for the purposes approved, by the Welsh Ministers;

(n) the chemist keeps a copy of the record mentioned in sub-paragraph (h) for at least two years after the date on which the consultation to which the record relates is carried out;

(o) MUR services are only to be provided to patients who are being prescribed more than one drug, unless the only drug they are being prescribed is a high risk medicine; and

(p) the chemist must obtain from each patient to whom he or she provides MUR services a signed consent form to receiving those services, which —

(i) includes the approved wording as regards consent which indicates that the patient has consented to receive those services ("approved" for these purposes means approved by the Welsh Ministers), and

(ii) amongst other matters indicates that the patient has either consented or does not consent to particular information, specified in the form, relating to MUR services provided to the patient being handled in the manner specified in the form (for example, for the purposes of post payment verification), and

the chemist must not provide MUR services to a patient unless the patient has consented to receive those services in accordance with sub-paragraph (p)(i); and may only handle particular information, specified in the form, in the manner specified in the form where the patient has provided consent in accordance with sub-paragraph (p)(ii).".

(7) After paragraph (6) insert the following —

"(7) As regards the financial year ending 31st March 2012, the chemist need only ensure that at least 50% of the MUR services consultations carried out by the chemist at or from the pharmacy on and after 1 December 2011 are carried out with patients who are in one or more of the national target groups set out in Schedule B.".

Insertion of Direction 5, Direction 6 and Direction 7 into the Principal Directions

4.After Direction 4 (Enhanced Services) of the Principal Directions insert the following —

"Advanced Services: Discharge Medicines Review Service general matters and preconditions for making arrangements

5.—(1) Each Local Health Board must make arrangements for the provision of a discharge medicines review service ("DMR service") for persons within and outside its area with any chemist included in its pharmaceutical list who —

(a) meets the conditions set out in paragraphs (3) to (9); and

(b) wishes to enter into such arrangements.

(2) The underlying purpose of the DMR service is, with the patient's agreement, to contribute to a reduction in risk of medication errors and adverse drug events by, in particular —

(a) increasing the availability of accurate information about a patient's medicines;

(b) improving communication between healthcare professionals and others involved in the transfer of patient care, and patients and their carers;

(c) increasing patient involvement in their own care by helping them to develop a better understanding of their medicines; and

(d) reducing the likelihood of unnecessary or duplicated prescriptions being dispensed thereby reducing wastage of medicines.

(3) The first condition is that the chemist has notified the Local Health Board of his or her intention to provide services as part of the DMR service, in the form(**1**) approved for that purpose by the Welsh Ministers.

(4) The second condition is that the chemist is satisfactorily complying with his or her obligations under Schedule 2 to the Pharmaceutical Services Regulations(**2**) in respect of the provision of essential services and an acceptable system of clinical governance.

(5) The third condition is that —

(a) if the chemist is a registered pharmacist, that he or she has an MUR certificate;

(b) if the chemist is a registered pharmacist, but he or she intends to employ or engage a registered pharmacist to perform services as part of the DMR service, that registered pharmacist has an MUR certificate; or

(c) if the chemist is not a natural person, any registered pharmacist her or she intends to employ or engage to perform services as part of the DMR service has an MUR certificate.

(6) The fourth condition is that —

(a) if the chemist is a registered pharmacist, that he or she completes in the approved manner the approved form warranting that the chemist is competent to perform services as part of the DMR service; or

(b) if the chemist is a registered pharmacist, but he or she intends to employ or engage a registered pharmacist to perform services as part of the DMR service, that registered pharmacist completes in the approved manner the approved form warranting that they are competent to perform services as part of the DMR service; or

(c) if the chemist is not a natural person, any registered pharmacist he or she intends to employ or engage to perform services as part of the DMR service completes in the approved manner the approved form warranting that they are competent to perform services as part of the DMR service,

and "approved" for these purposes means approved by the Welsh Ministers.

(7) The fifth condition is that the chemist has in place a standard operating procedure, at the pharmacy at or from which services as part of the DMR service are to be delivered, for delivery of the service —

(a) which has been notified to the pharmacy staff;

(b) which explains the service, eligibility criteria for it and the roles that pharmacy staff may be required to perform as part of it; and

(c) about which staff have received appropriate training, if there is any role that they may be asked to perform as part of the service.

(8) Subject to paragraph (9), the sixth condition is that the services provided as part of the DMR service are provided at an acceptable location, and for these purposes, "acceptable location" means an area for confidential consultations at the chemist's pharmacy, which is —

(**1**) Advanced services specifications and forms can be accessed at http://www.wales.nhs.uk/sites3/page.cfm?orgid=498&pid=7551

(**2**) "Pharmaceutical Services Regulations" are defined in Direction 2 of the principal Directions as the National Health Service (Pharmaceutical Services) Regulations 1992.

(a) clearly designated as an area for confidential consultations;

(b) distinct from the general public areas of the pharmacy; and

(c) an area where both the person receiving services as part of the DMR service and the registered pharmacist providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person (including pharmacy staff),

except that sub-paragraphs (a) and (b) shall not apply in circumstances where the pharmacy is closed to other members of the public.

(9) A registered pharmacist who is, or who is employed or engaged by the chemist may provide services as part of the DMR service other than at the acceptable location at the chemist's pharmacy if that registered pharmacist does so —

(a) by telephone to a particular patient on a particular occasion,

(b) with the agreement of that patient, that patient having expressed a preference for that contact to be by telephone on that occasion, and

(c) in circumstances where —

(i) the registered pharmacist is at the chemist's pharmacy, and

(ii) the telephone conversation cannot be overheard (except by someone whom the patient wants to hear the conversation, for example a carer); or

(d) in a location other than the chemist's pharmacy only with the consent of the Local Health Board.

Advanced Services: Discharge Medicines Review Service ongoing conditions of arrangements

6.—(1) A Local Health Board making arrangements pursuant to direction 5(1) with a chemist must ensure that those arrangements provide that —

(a) only a registered pharmacist —

(i) with an MUR certificate, and

(ii) who has completed in the approved manner the approved form warranting that they are competent to perform services as part of the DMR service,

may perform services as part of the DMR service;

(b) the services are only provided as part of the DMR service at an acceptable location at the chemist's pharmacy, within the meaning given in direction 5(8), except in the circumstances provided for in direction 5(9);

(c) where services are provided as part of the DMR service other than at the acceptable location at the chemist's pharmacy, they are only provided —

(i) by telephone to a particular patient on a particular occasion,

(ii) with the agreement of that patient, that patient having expressed a preference for that contact to be by telephone on that occasion, and

(iii) in circumstances where —

(aa) the pharmacist is at the chemist's pharmacy, and

(bb) the telephone conversation cannot be overheard (except by someone whom the patient wants to hear the conversation, for example a carer); or

(iv) in a location other than the chemist's pharmacy only with the consent of the Local Health Board.

(d) the chemist maintains and keeps under review its standard operating procedure, at the pharmacy at or from which services as part of the DMR service are to be delivered, for delivery of those services, and —

(i) any changes to it are notified to the pharmacy staff,

(ii) the procedure explains the service, eligibility criteria for it and the roles that pharmacy staff may be required to perform as part of it, and

(iii) staff receive appropriate training about the service, if there is any role they may be asked to perform as part of the service;

(e) the chemist only offers to provide the service as part of their DMR service to persons who have within the previous 4 weeks been discharged from one care setting to another, and —

(i) the pharmacy has received a copy of any advice note, regarding the patient's medicines, issued from the care setting from which the patient has been discharged, and

(ii) a change has occurred to the patient's medicines prior to discharge, or

(iii) the patient is taking four or more medicines, or

(iv) the patient requires a reasonable adjustment to be made to the presentation of their medicines, or

(v) the pharmacist has, in their professional opinion, reason to consider that the patient would benefit from the service;

(f) the part one services that the chemist provides as part of the DMR service must comprise —

(i) providing the patient with sufficient information about the DMR service to enable them to give their informed consent to receiving the service,

(ii) obtaining from the patient a signed consent form to receiving services, which —

(aa) includes the approved wording as regards consent which indicates that the patient has consented to receive those services ("approved" for these purposes means approved by the Welsh Ministers), and

(bb) amongst other matters, indicates that the patient has either consented or does not consent to particular information, specified in the form, relating to DMR services provided to the patient being handled in the manner specified in the form (for example, for the purposes of post payment verification), and

the chemist may not provide DMR services to a patient unless the patient has consented to receive those services in accordance with sub-paragraph (f)(ii)(aa); and may only handle particular information, specified in the form, in the manner specified in the form where the patient has provided consent in accordance with sub-paragraph (f)(ii)(bb),

(iii) a discussion with the patient about the medicines the patient is taking,

(iv) identification, by the registered pharmacist performing the service, of any discrepancies between the medicines the patient is taking and those prescribed at discharge, and

(v) agreement (where possible) between the registered pharmacist and the patient of the next steps, that is —

(aa) if no discrepancies between the medicines the patient is taking and those prescribed at discharge are agreeing with the patient a time and location for the part two services,

(bb) if any discrepancies or problems are identified under paragraph (iv) and it is the clinical judgement of the registered pharmacist that intervention by the patient's general practitioner is warranted, explaining that to the patient, completing the DMR feedback form (which is in a format approved by the Welsh Ministers) and referring the matter to the patient's general practitioner,

(cc) if any discrepancies or problems are identified under paragraph (iv) but it is the clinical judgement of the registered pharmacist that intervention by the patient's general practitioner is not warranted, agreeing with the patient a time and location for the part two services and any appropriate remedial steps to be taken prior to that intervention;

(g) the part two services that the chemist provides as part of their DMR service must comprise —

(i) a discussion with the patient about the medicines the patient is taking,

(ii) an assessment by the registered pharmacist performing the part two services of the extent to which any discrepancies between the medicines the patient is taking and those prescribed at discharge have been resolved,

(iii) a service consultation which meets the requirements of Direction 3 (Advanced services: Medicines Use Review and Prescription Intervention Services), and

(iv) if any problems are identified under paragraph (ii) and it is the clinical judgement of the registered pharmacist that intervention by the patient's general practitioner is warranted, explaining that to the patient, completing the DMR form (which is in a format approved by the Welsh Ministers) and referring the matter to the patient's general practitioner;

(h) the Local Health Board must terminate the arrangements if it is on notice that the chemist is not, or no longer, satisfactorily complying with his or her obligations under Schedule 2 to the Pharmaceutical Services Regulations in respect of the provision of essential services and an acceptable system of clinical governance;

(i) the chemist ensures that a written record (which may be an electronic record) of each consultation carried out by or on behalf of the chemist as part of his or her DMR service is prepared by the registered pharmacist who carried out the consultation and includes the approved data ("approved" for these purposes means approved by the Welsh Ministers);

(j) the chemist provides information from those records to the Local Health Board, the NHS Wales Shared Services Partnership or the Welsh Ministers, on request, in the manner approved for this purpose, and for the purposes approved, by the Welsh Ministers; and

(k) the chemist keeps a copy of the record mentioned in sub-paragraph (i) for at least 2 years from the date on which the service intervention is completed or discontinued.

(2) For the purposes of paragraph (1)(f) and (g), a full service has been completed —

(a) once the patient has received the part one and part two services; or

(b) if, as a consequence of an act or omission of the patient, the patient does not receive the part two services at the agreed time and the chemist is unable, having made reasonable efforts to do so, to rearrange and provide those part two services on another occasion, once those reasonable efforts have been made.

Duration of Discharge Medicines Review Service

7. Directions 5 and 6 cease to have effect at the end of 31 March 2013.".

Insertion of Schedule B into the Principal Directions

5.Schedule B which is set out in the Schedule to these Directions is inserted into the Principal Directions.

Transitional arrangements

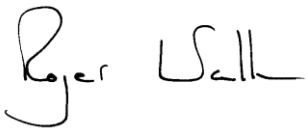
6.—(1) This Direction has effect only in relation to Direction 3 of these Directions.

(2) The amendments to Direction 3 (Advanced Services: Medicines Use Review and Prescription Intervention Service) of the principal Directions made by these Directions shall not have effect in relation to arrangements for the provision of MUR services at any time before the end of the transitional period by a chemist whose name was, immediately before these Directions came into force, already on a pharmaceutical list maintained by a Local Health Board under the Pharmaceutical Services Regulations provided that —

(a) the chemist chooses to comply and does comply with the provisions of Direction 3 of the principal Directions as they had effect prior to the amendment by these Directions; and

(b) at the end of the transitional period the chemist complies with Direction 3 of the principal Directions as amended by these Directions.

(3) In this Direction, "transitional period" means the period that begins on the day that these Directions come into force and ends at the end of 1 December 2011.



Signed by Professor Roger Walker, Chief Pharmaceutical Officer, under the authority of the Minister for Health and Social Services, one of the Welsh Ministers

Date: 31 October 2011

SCHEDULE

Direction 5

"SCHEDULE B

Direction3

National Target Groups for MUR Services

1. Patients taking a high risk medicine, and for these purposes, "high risk medicine" is a medicine included in the BNF subsections referenced in the table in this paragraph—

BNF Reference	*BNF subsection descriptor*
BNF 10.1.1	NSAIDs
BNF 2.8.2	Oral anticoagulants
BNF 2.9	Antiplatelets
BNF 2.2	Diuretics

2. For these purposes, "high risk medicine" is a medicine referenced in the table in this paragraph—

BNF Reference	*BNF subsection descriptor*
BNF 4.2.3	Lithium
BNF 10.1.3	Methotrexate

3. Patients prescribed a respiratory drug included in the BNF subsections referenced in the table in this paragraph—

BNF Reference	*BNF subsection descriptor*
BNF 3.1.1	Adrenoreceptor agonists
BNF 3.1.2	Antimuscarinic bronchodilators
BNF 3.1.3	Theophylline
BNF 3.1.4	Compound bronchodilator preparations
BNF 3.2	Corticosteroids
BNF 3.3	Cromoglicate and related therapy, leukotriene receptor antagonists and phosphodiesterase type-4 inhibitors

4. Patients with hypertension prescribed an antihypertensive drug included in the BNF subsections referenced in the table in this paragraph—

BNF Reference	*BNF subsection descriptor*
BNF 2.2.1	Thiazides and related diuretics
BNF 2.4	Beta-adrenoreceptor blocking drugs
BNF 2.5.2	Centrally acting antihypertensive drugs
BNF 2.5.4	Alpha-adrenoreceptor blocking drugs
BNF 2.5.5	Drugs affecting the renin-angiotensin system
BNF 2.6.2	Calcium-channel blockers

5. Patients prescribed a medicine no longer required identified and who fit one of the descriptors in the table in this paragraph—

Group	*Descriptor*
Repeat prescriptions are not synchronised	Patients present on multiple occasions each month to collect prescriptions.
"When required" medicines are ordered routinely	Patients routinely order medicines prescribed *'prn'* and which would normally be taken only when required.
Medicines waste is returned to the pharmacy	Patients return unused medicines for disposal. ”