
D I R E C T I O N S

THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2011

The Secretary of State gives the following Directions in exercise of the powers conferred by sections 8, 127, 128, 272(7) and (8) and 273(1) of the National Health Service Act 2006(a).

CONTENTS

PART 1

Introductory

1. Citation, commencement and application
2. Interpretation
3. Revocations

PART 2

Advanced services: pharmacy contractors only

4. MUR services: general matters and pre-conditions for making arrangements
5. MUR services: ongoing conditions of arrangements
6. New Medicine Service: general matters and preconditions for making arrangements
7. New Medicine Service: ongoing conditions of arrangements
8. Duration of New Medicine Service

PART 3

Advanced services: appliances

9. Establishing and maintaining stoma appliance customisation services
10. Requirements applying to stoma customisation services
11. Establishing and maintaining appliance use review services for specified appliances
12. Requirements applying to appliance use review services
13. Maximum number of appliance use review services eligible for payment

PART 4

Enhanced services: pharmacy contractors only

14. Enhanced services provided by pharmacy contractors

SCHEDULE 1 — National Target Groups for MUR services

SCHEDULE 2 — NMS medicines

PART 1

Introductory

Citation, commencement and application

1.—(1) These Directions may be cited as the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2011 and come into force on 1st October 2011.

(2) These Directions are given to Primary Care Trusts in England.

Interpretation

2. In these Directions—

“the Act” means the National Health Service Act 2006;

“appliance contractor” means a person included in a list prepared under regulation 4(1)(b) of the Pharmaceutical Services Regulations (preparation of lists);

“AUR service” is to be construed in accordance with direction 11(1);

“BNF” means the current edition of British National Formulary, as amended from time to time(a);

“clinical management plan” has the same meaning as in the POM Order;

“Drug Tariff” has the meaning given in regulation 56(a) of the Pharmaceutical Services Regulations;

“drugs” includes medicines;

“financial year” means the period of 12 months ending on 31st March in any year;

“general practitioner”, in relation to a patient, means any medical practitioner who is, or who is a member of, a provider of primary medical services that holds the registered patient list on which the patient is a registered patient;

“gluten free foods” means only those gluten free foods that are listed in Part XV of the Drug Tariff (borderline substances);

“high risk medicine” has the meaning given in paragraph 1 of Schedule 1;

“health care professional” means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(b) (the Council for Healthcare Regulatory Excellence);

“MUR certificate” means a statement of satisfactory performance certificate awarded or endorsed by a higher education institute being evidence that a person has satisfactorily completed an assessment relating to the competency framework for registered pharmacists providing MUR services approved by the Secretary of State(c);

(a) The British National Formulary is one of the specified publications mentioned in section 103(1) of the Medicines Act 1968 (c. 67), and so in accordance with subsection (3) of that section, the references in these Directions to the current edition of that Formulary, as amended from time to time, are to the most up to date version of the Formulary at any given time. The Formulary is available at www.bnf.org.

(b) 2002 c.17. Subsection (3) has been amended by the Health and Social Care Act 2008 (c. 14), section 113(2) and Schedule 10, paragraph 17, and by S.I. 2010/231. The Council’s name was changed to the Council for Healthcare Regulatory Excellence by section 113(1) of the Health and Social Care Act 2008.

(c) The competency framework is published by the Department of Health on its website, www.dh.gov.uk.

“MUR services” is to be construed in accordance with direction 4(1);

“NHS BSA” means the NHS Business Services Authority established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(a);

“NMS medicine” has the meaning given in paragraph 1 of Schedule 2;

“out of hours period” means, in relation to a pharmacy, the periods of time that are not part of the hours during which pharmacy must be open by virtue of paragraph 22(1) of Schedule 1 to the Pharmaceutical Services Regulations(b) (pharmacy opening hours: general) (these hours are often referred to as core opening hours);

“the Pharmaceutical Services Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2005(c);

“pharmacist independent prescriber” has the same meaning as in the Pharmaceutical Services Regulations;

“pharmacy” has the same meaning as in the Pharmaceutical Services Regulations;

“pharmacy contractor” means a person included in a list prepared under regulation 4(1)(a) of the Pharmaceutical Services Regulations;

“POM Order” means the Prescription Only Medicines (Human Use) Order 1997(d);

“registered patient” means a patient who is included in a list that is a registered patient list for the purposes of the Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004(e);

“specialist nurse” means a person who is—

(a) registered in the Nurses’ Part or Specialist Community Public Health Nurses’ Part of the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(f) (establishment and maintenance of register); and

(b) employed or engaged by any pharmacist or supplier of appliances for the purposes of conducting a review of a person’s use of specified appliances;

“specified appliance” means—

(a) any of the following appliances listed in Part IXA of the Drug Tariff—

(i) a catheter appliance (including a catheter accessory and maintenance solution),

(ii) a laryngectomy or tracheostomy appliance,

(iii) an anal irrigation system,

(iv) a vacuum pump or constrictor ring for erectile dysfunction, or

(v) a wound drainage pouch;

(b) an incontinence appliance listed in Part IXB of the Drug Tariff; or

(c) a stoma appliance listed in Part IXC of the Drug Tariff; and

“stoma appliance customisation” means the customisation of a quantity of more than one stoma appliance, where—

(a) the stoma appliances to be customised are listed in Part IXC of the Drug Tariff;

(b) the customisation involves modification to the same specification of multiple identical parts for use with each appliance; and

(c) that modification is based on the patient’s measurements or record of those measurements and, if applicable, a template.

(a) S.I. 2005/2414.

(b) Paragraph 22 has been amended by S.I. 2006/3373 and 2009/2205.

(c) S.I. 2005/641.

(d) S.I. 1997/1830.

(e) S.I. 2004/906; *see* regulation 2(2) of those Regulations.

(f) S.I. 2002/253.

Revocations

3. The following Directions are revoked—

- (a) the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2005(a);
- (b) direction 3 of the National Health Service (Miscellaneous Amendments Relating to Prescribing, Pharmaceutical Services and Local Pharmaceutical Services etc.) (England) Directions 2006(b) (the amendments made by direction 3 have been republished in the Drug Tariff as the Pharmaceutical Services (Advanced and Enhanced Services) (England) Amendment Directions 2006, dated 8th March 2006, and accordingly, the republished version of the amendments also cease to have effect by virtue of this paragraph);
- (c) the Pharmaceutical Services (Advanced and Enhanced Services) (England) Amendment Directions 2006, which were signed on 15th September 2006(c);
- (d) the Pharmaceutical Services (Advanced and Enhanced Services) (England) Amendment Directions 2007(d); and
- (e) the Pharmaceutical Services (Advanced Services) (Appliances) (England) Directions 2009(e).

PART 2

Advanced services: pharmacy contractors only

MUR services: general matters and pre-conditions for making arrangements

4.—(1) Each Primary Care Trust must make arrangements for the provision of medicines use review and prescription intervention services (“MUR services”) for persons within or outside its area with any pharmacy contractor (P) on its pharmaceutical list who—

- (a) meets the conditions set out in paragraphs (3) to (5); and
- (b) wishes to enter into such arrangements or is required to do so by virtue of regulation 13(3) or 14 of the Pharmaceutical Services Regulations.

(2) The underlying purpose of MUR services is, with the patient’s agreement, to improve the patient’s knowledge and use of drugs by in particular—

- (a) establishing the patient’s actual use, understanding and experience of taking drugs;
- (b) identifying, discussing and assisting in the resolution of poor or ineffective use of drugs by the patient;
- (c) identifying side effects and drug interactions that may affect the patient’s compliance with instructions given to them by a health care professional for the taking of drugs; and
- (d) improving clinical and cost effectiveness of drugs prescribed to patients, thereby reducing the wastage of such drugs.

(3) Condition 1 is that P is satisfactorily complying with P’s obligations under Schedule 1 to the Pharmaceutical Services Regulations in respect of the provision of essential services and an acceptable system of clinical governance.

(4) Condition 2 is that—

- (a) if P is a registered pharmacist—
 - (i) P has an MUR certificate, or

(a) Signed on 31st March 2005. The relevant amending Directions are the other Directions listed in this direction.

(b) Signed on 8th March 2006.

(c) The other Directions that are cited with this name cease to have effect by virtue of the previous paragraph of this direction.

(d) Signed on 10th December 2007.

(e) Signed on 16th December 2009.

- (ii) if P intends to employ or engage a registered pharmacist to perform MUR services, that registered pharmacist has an MUR certificate; or
 - (b) if P is not a natural person, any registered pharmacist P intends to employ or engage to perform MUR services has an MUR certificate,
- and P has supplied a copy of such certificates to the Primary Care Trust prior to entering into an arrangement to provide MUR services.

(5) Subject to paragraph (6), condition 3 is that the MUR services are provided at an acceptable location, and for these purposes, “acceptable location” means—

- (a) an area for confidential consultations at P’s pharmacy, which is—
 - (i) clearly designated as an area for confidential consultations,
 - (ii) distinct from the general public areas of the pharmacy, and
 - (iii) an area where both the person receiving MUR services 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 paragraphs (i) and (ii) shall not apply in circumstances where the pharmacy is closed to other members of the public;
- (b) an area for confidential consultations which is not at P’s pharmacy, which is—
 - (i) clearly designated as an area for confidential consultations,
 - (ii) distinct from the general public areas of the premises in which it is situated, and
 - (iii) an area where both the person receiving MUR services 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,and the Primary Care Trust has approved the premises where the area is situated as being premises at which MUR services may be provided (and that approval has not been withdrawn); or
- (c) premises to which neither sub-paragraph (a) or (b) applies, but which are—
 - (i) premises as regards which P has obtained the approval of the Primary Care Trust to provide MUR services to a particular patient on a particular occasion, or
 - (ii) premises or a category of premises as regards which P has obtained the approval of the Primary Care Trust (which has not been withdrawn) to provide MUR services to a particular category of patients, in such circumstances and subject to such conditions as the Primary Care Trust may have specified (which the Primary Care Trust may vary without withdrawing its approval).

(6) A registered pharmacist who is, or who is employed or engaged by, P may provide MUR services other than at an acceptable location if that registered pharmacist does so—

- (a) by telephone to a particular patient on a particular occasion; and
- (b) in circumstances where the telephone conversation cannot be overheard (except by someone whom the patient wants to hear the conversation, for example a carer),

but only if P has obtained the approval of the Primary Care Trust to do so on that particular occasion.

MUR services: ongoing conditions of arrangements

5.—(1) A Primary Care Trust making arrangements pursuant to direction 4(1) with a pharmacy contractor (P) must ensure that those arrangements provide that—

- (a) only a registered pharmacist with an MUR certificate, a copy of which has been supplied to P’s Primary Care Trust, may perform MUR services;
- (b) MUR services are only provided—
 - (i) at an acceptable location within the meaning given in direction 4(5), excepted in the circumstances provided for in direction 4(6), and

- (ii) at a location for which the Primary Care Trust's approval is required by virtue of direction 4(5)(b) or (c), if the necessary approval has been given by the Primary Care Trust and has not been withdrawn;
- (c) where MUR services are provided other than at an acceptable location within the meaning given in direction 4(5), they are only provided—
 - (i) by telephone to a particular patient on a particular occasion, and
 - (ii) in circumstances where the telephone conversation cannot be overheard (except by someone whom the patient wants to hear the conversation, for example a carer), with P having obtained the approval of the Primary Care Trust to do so on that particular occasion;
- (d) subject to paragraph (2), no more than 400 MUR services consultations are carried out under the arrangements in any financial year (whether at an acceptable location or by telephone);
- (e) an MUR services consultation which is not triggered by concerns over patient adherence must not be offered to a patient unless the patient has been receiving pharmaceutical services from P at or from the pharmacy for a period of at least 3 consecutive months;
- (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 New Medicine 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;
- (g) subject to paragraph (5), at least 50% of the MUR services consultations carried out by P 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 1;
- (h) P ensures that a written record of each MUR service consultation carried out by or on behalf of P is prepared by the registered pharmacist who carried out the consultation, on the approved form or in the approved manner and including the approved data ("approved" for these purposes means approved by the Secretary of State);
- (i) where the record mentioned in sub-paragraph (h) has to be on an approved form, P provides a copy of that form to the patient with whom the consultation to which it relates was carried out;
- (j) P provides information from the record mentioned in sub-paragraph (h) to the Primary Care Trust or the Secretary of State, on request, in the manner approved for this purpose, and for the purposes approved, by the Secretary of State;
- (k) P provides, in respect of each MUR service consultation carried out with a patient by or on behalf of P, to any provider of primary medical services of which that patient is a registered patient—
 - (i) a copy of the record mentioned in sub-paragraph (h),
 - (ii) a copy of part of, or information derived from, that record, or
 - (iii) a notification that the patient has received MUR services,
 whichever of these is advised, and in accordance with the time limits advised, in "Guidance on the Provision of MUR Service Consultation Record", issued by the Secretary of State^(a);

(a) Dated 14th December 2007.

- (l) P 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;
- (m) the Primary Care Trust must terminate the arrangements if it is on notice that P is not, or no longer, satisfactorily complying with P's obligations under Schedule 1 to the Pharmaceutical Services Regulations in respect of the provision of essential services and an acceptable system of clinical governance;
- (n) 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
- (o) P must obtain from each patient to whom P provides MUR services a signed consent form to receiving those services, which—
 - (i) includes the approved wording as regards consent ("approved" for these purposes means approved by the Secretary of State), and
 - (ii) amongst other matters, indicates the patient's 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 P must not provide MUR services to a patient unless the patient's consent to that information being handled in the manner specified has been obtained.

(2) As regards the first financial year during which any arrangements made with a pharmacy contractor to provide MUR services have effect, paragraph (1)(d) shall apply as if for "400" were substituted "200" if the arrangements only take effect on or after 1st October of that financial year.

(3) For the purposes of paragraph (2), arrangements with P to provide MUR services at or from a particular location are to be treated as taking effect once P has—

- (a) notified the Primary Care Trust in writing that P intends to start providing the MUR services; and
- (b) supplied the Primary Care Trust with copies of any MUR certificates that P is required to supply in order to satisfy the condition in direction 4(4).

(4) A form approved by the Secretary of State pursuant to paragraph (1)(h) may be in the form of an electronic record and may be sent or stored electronically (an approved manner may also provide for electronic storage and transmission of the approved data set).

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

New Medicine Service: general matters and preconditions for making arrangements

6.—(1) Each Primary Care Trust must make arrangements for the provision of a New Medicine Service for persons within and outside its area with any pharmacy contractor (P) on its pharmaceutical list who—

- (a) meets the conditions set out in paragraphs (3) to (9); and
- (b) wishes to enter into such arrangements or is required to do so by virtue of regulation 13(3) or 14 of the Pharmaceutical Services Regulations.

(2) The underlying purpose of a New Medicine Service is to promote the health and well being of patients prescribed with new medicines for long term conditions, in order—

- (a) as regards the long term conditions—
 - (i) to help reduce symptoms and long term complications, and
 - (ii) in particular by intervention post dispensing, to help identification of problems with management of the condition and the need for further information or support; and
- (b) to help the patients—
 - (i) make informed choices about their care,

- (ii) self-manage their long term conditions,
- (iii) adhere to agreed treatment programmes, and
- (iv) make appropriate life style changes.

(3) Condition 1 is that P has notified the Primary Care Trust of P's intention to provide services as part of a New Medicine Service, in the form approved for that purpose by the Secretary of State.

(4) Condition 2 is that P is satisfactorily complying with P's obligations under Schedule 1 to the Pharmaceutical Services Regulations in respect of the provision of essential services and an acceptable system of clinical governance^(a).

(5) Condition 3 is that—

- (a) if P is a registered pharmacist—
 - (i) P has an MUR certificate, or
 - (ii) if P intends to employ or engage a registered pharmacist to perform services as part of a New Medicine Service, that registered pharmacist has an MUR certificate; or
- (b) if P is not a natural person, any registered pharmacist P intends to employ or engage to perform services as part of a New Medicine Service has an MUR certificate.

(6) Condition 4 is that—

- (a) if P is a registered pharmacist—
 - (i) P completes in the approved manner the approved form warranting that P is competent to perform services as part of a New Medicine Service, or
 - (ii) if P intends to employ or engage a registered pharmacist to perform services as part of a New Medicine Service, that registered pharmacist completes in the approved manner the approved form warranting that they are competent to perform services as part of a New Medicine Service; or
- (b) if P is not a natural person, any registered pharmacist P intends to employ or engage to perform services as part of a New Medicine Service completes in the approved manner the approved form warranting that they are competent to perform services as part of a New Medicine Service,

and “approved” for these purposes means approved by the Secretary of State.

(7) Condition 5 is that P has in place a standard operating procedure, at the pharmacy at or from which services as part of a New Medicine Service is 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) Condition 6 is that P must have notified providers of primary medical services in their locality of P's intention to provide services as part of a New Medicine Service.

(9) Subject to paragraph (10), condition 7 is that second and third stage services provided as part of the New Medicine Service are provided at an acceptable location, and for these purposes, “acceptable location” means an area for confidential consultations at P's pharmacy, which is—

- (a) clearly designated as an area for confidential consultations;
- (b) distinct from the general public areas of the pharmacy; and

(a) Pharmacy contractors who are already providing pharmaceutical services at a particular pharmacy on 1st October 2011 have until the end of 31st March 2012 to implement at that pharmacy the changes made to paragraph 26 of Schedule 1 to the Pharmaceutical Services Regulations on 1st October 2011, without breaching the requirements of that paragraph by failing to implement them.

- (c) an area where both the person receiving services as part of the New Medicine 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.

(10) A registered pharmacist who is, or who is employed or engaged by, P may provide second and third stage services as part of a New Medicine Service other than at the acceptable location at P'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 P'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).

New Medicine Service: ongoing conditions of arrangements

7.—(1) A Primary Care Trust making arrangements pursuant to direction 6(1) with a pharmacy contractor (P) 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 a New Medicine Service, may perform services as part of a New Medicine Service;
- (b) second and third stage services are only provided as part of a New Medicine Service at an acceptable location at P's pharmacy, within the meaning given in direction 6(9), except in the circumstances provided for in direction 6(10);
- (c) where second and third stage services are provided as part of a New Medicine Service other than at the acceptable location at P's pharmacy, they are only provided—
 - (i) by telephone to a particular patient on a particular occasion, and
 - (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 P'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);
- (d) P maintains and keeps under review its standard operating procedure, at the pharmacy at or from which services as part of a New Medicine 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) P only offers to provide first stage services as part of their New Medicine Service (and so only offers to provide any part of the service) to persons who have, for the first time, been prescribed a particular NMS medicine (Schedule 2 lists these drugs), and—

- (i) the prescription is on a prescription form (within the meaning given in the Pharmaceutical Services Regulations^(a)) and is presented at the pharmacy premises at or from which the service is to be provided, or
- (ii) the prescribing occurred while the patient was at a hospital (whether as an inpatient or an outpatient), but—
 - (aa) as part of a course of treatment that is to continue once the patient is no longer at the hospital, and
 - (bb) the patient was referred to P by a health care professional at the hospital who is (partly) responsible for that course of treatment;
- (f) the first stage services that P provides as part of the New Medicine Service (either with the patient at P's pharmacy or, provided that the registered pharmacist is at P's pharmacy and to the extent possible, by telephone) must comprise—
 - (i) agreeing with the patient who is being offered the service (whether as a consequence of prescriber referral or of P's own motion)—
 - (aa) when P dispenses the newly prescribed NMS medicine to the patient, or
 - (bb) in a case to which sub-paragraph (e)(ii) applies, when the patient contacts P about the service as a consequence of the referral mentioned in sub-paragraph (e)(ii)(bb),
 a time and location for the second stage intervention services (which may be a split location),
 - (ii) providing the patient with sufficient information about the New Medicine Service (for example, in a leaflet) to enable them to give their informed consent to receiving the service,
 - (iii) obtaining from the patient a signed consent form to receiving services as part of P's New Medicine Service, which—
 - (aa) includes the approved wording as regards consent ("approved" for these purposes means approved by the Secretary of State), and
 - (bb) amongst other matters, indicates the patient's consent to particular information, specified in the form, relating to services provided to the patient as part of the New Medicine Service being handled in the manner specified in the form (for example, for the purposes of post payment verification), and
 - (iv) as appropriate, providing the patient with information relevant to the objectives listed in direction 6(2) (where this is not already required under Part 2 of Schedule 1 to the Pharmaceutical Services Regulations);
- (g) P must discontinue providing services to a patient as part of the New Medicine Service if the patient refuses to consent to the information mentioned in sub-paragraph (f)(iii)(bb) being handled in the manner specified in the form mentioned in that sub-paragraph, or if that consent is withdrawn prior to the completion of a full service intervention;
- (h) the second stage services that P provides as part of their New Medicine Service must comprise—
 - (i) a discussion with the patient about whether or not they wish to withdraw the consent attested to in the form mentioned in sub-paragraph (f)(iii),
 - (ii) assessment by the registered pharmacist performing the second stage services of the adherence by the patient to their treatment programme for the relevant NMS medicine,
 - (iii) identification of any problems either with the treatment (including any adverse drug reactions) or otherwise in relation to the patient's self-management of their long term

(a) See regulation 2(1) of those Regulations.

condition, and identification of any need of the patient for further information and support in relation to the treatment or the long term condition,

- (iv) agreement (where possible) between the registered pharmacist and the patient of the next steps, that is—
 - (aa) if the patient is adhering to the treatment programme for the relevant NMS medicine and no problems are identified under paragraph (iii), agreeing with the patient a time and location for third stage services (which may be a split location),
 - (bb) if any problems are identified under paragraph (iii) 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 NMS feedback form (which is in a format approved by the Secretary of State) and referring the matter to the patient's general practitioner (which amounts to a full service intervention in respect of that patient, unless the second stage services are being provided in respect of more than one medicine and the referral to the general practitioner does not relate to the use of every medicine in respect of which the service is being provided),
 - (cc) if any problems are identified under paragraph (iii) but it is the clinical judgement of the registered pharmacist that intervention by the patient's general practitioner is not warranted (or not warranted in relation to every medicine in respect of which the second stage services are being provided), agreeing with the patient a time and location for third stage services (which may be a split location in the event of an intervention by telephone) and any appropriate remedial steps to be taken prior to that intervention, and
- (v) as appropriate, providing the patient with other information relevant to the objectives listed in direction 6(2) (where this is not already required under Part 2 of Schedule 1 to the Pharmaceutical Services Regulations);
- (i) P must discontinue providing services to a patient as part of the New Medicine Service if, as a consequence of an act or omission of the patient, the patient does not receive the second stage services at the agreed time and P is unable, having made reasonable efforts to do so, to rearrange and provide those second stage services on another occasion;
- (j) the third stage services that P provides as part of their New Medicine Service must comprise—
 - (i) assessment by the registered pharmacist performing the third stage services of the adherence by the patient to their treatment programme for the relevant NMS medicine,
 - (ii) identification of any new or continuing problems either with the treatment (including any adverse drug reactions) or otherwise in relation to the patient's self-management of their long term condition, and identification of any need of the patient for further information and support in relation to the treatment or the long term condition,
 - (iii) 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 NMS feedback form (which is in a format approved by the Secretary of State) and referring the matter to the patient's general practitioner, and
 - (iv) as appropriate, providing the patient with other information relevant to the objectives listed in direction 6(2) (where this is not already required under Part 2 of Schedule 1 to the Pharmaceutical Services Regulations),
unless a full service intervention has been completed prior to P being able to make the assessment referred to in paragraph (i);
- (k) the Primary Care Trust must terminate the arrangements if it is on notice that P is not, or no longer, satisfactorily complying with P's obligations under Schedule 1 to the

Pharmaceutical Services Regulations in respect of the provision of essential services and an acceptable system of clinical governance;

- (l) P ensures that a written record (which may be an electronic record) of each consultation carried out by or on behalf of P as part of P's New Medicine 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 Secretary of State);
 - (m) P provides information from those records to the Primary Care Trust or the Secretary of State, on request, in the manner approved for this purpose, and for the purposes approved, by the Secretary of State; and
 - (n) P keeps a copy of the record mentioned in sub-paragraph (l) for at least 2 years from the date on which the service intervention is completed or discontinued.
- (2) For the purposes of paragraph (1)(g) and (j), a full service intervention has been completed—
- (a) once a patient is referred to their general practitioner as mentioned in paragraph (1)(h)(iv)(bb);
 - (b) following the assessment made under paragraph (1)(j)(i)—
 - (i) if the patient is adhering to the treatment programme for the relevant NMS medicine and no problems are identified under paragraph (1)(j)(ii), once the assessment has been made and (where applicable) any further information has been provided as mentioned in paragraph (1)(j)(iv), or
 - (ii) if problems are identified under paragraph (1)(j)(ii), if—
 - (aa) it is the clinical judgement of the registered pharmacist that intervention by the patient's general practitioner is warranted, once that referral has been made, or
 - (bb) it is the clinical judgement of the registered pharmacist that intervention by the patient's general practitioner is not warranted, once any appropriate advice in relation to the new or continuing problems has been given and (where applicable) any further information has been provided as mentioned in paragraph (1)(j)(iv); or
 - (c) if, as a consequence of an act or omission of the patient, the patient does not receive the third stage services at the agreed time and P is unable, having made reasonable efforts to do so, to rearrange and provide those third stage services on another occasion, once those reasonable efforts have been made.

Duration of New Medicine Service

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

PART 3

Advanced services: appliances

Establishing and maintaining stoma appliance customisation services

9.—(1) Each Primary Care Trust must make arrangements for the provision of stoma appliance customisation services for persons within or outside its area by any pharmacy contractor (P) or appliance contractor (S)—

- (a) who is on the Primary Care Trust's pharmaceutical list;
- (b) who supplies stoma appliances listed in Part IXC of the Drug Tariff in the normal course of business;
- (c) who either wishes to enter into the arrangements or is required to do so by virtue of regulation 13(3) or 14 of the Pharmaceutical Services Regulations; and

- (d) in relation to whom—
 - (i) Conditions 1, 2 and 3 are met, and
 - (ii) if services are to be provided elsewhere than at P’s pharmacy or S’s premises, Condition 4 is also met.
- (2) The underlying purpose of a stoma appliance customisation service is to—
 - (a) ensure the proper use and comfortable fitting of the stoma appliance by a patient; and
 - (b) improve the duration of usage of the appliance, thereby reducing wastage of such appliances.
- (3) Condition 1 is that, before any arrangements are entered into, the Primary Care Trust and the NHS BSA have each been supplied with notice that P or S wishes to provide stoma appliance customisation services.
- (4) Condition 2 is that P or S—
 - (a) is satisfactorily complying with P’s obligations under Schedule 1 to the Pharmaceutical Services Regulations or S’s obligations under Schedule 3 to those Regulations (as the case may be); and
 - (b) has procedures in place to ensure referral of a patient to the prescriber of the appliance in any case where—
 - (i) a customised stoma appliance is not suitable for further customisation, or
 - (ii) a stoma appliance has been customised and is not a proper fit for the patient.
- (5) Condition 3 is that stoma appliance customisation services must be provided at an acceptable location and, for these purposes, an “acceptable location” means—
 - (a) an area within P’s pharmacy or S’s premises which—
 - (i) is distinct from the general public areas,
 - (ii) at all times when stoma appliance customisation services are being provided, is clearly designated as a private area,
 - (iii) is suitable and designated for the retention of the appropriate equipment for stoma appliance customisation,
 - (iv) is suitable and designated for the carrying out of modification of stoma appliances, and
 - (v) is suitable and designated for the volume of stoma appliances that may be customised at any given time; or
 - (b) an area elsewhere than at P’s pharmacy or S’s premises which—
 - (i) is distinct from the general public areas of the premises in which it is situated, and
 - (ii) meets the requirements of paragraph (a)(ii) to (v).
- (6) Condition 4 is that, in any case where any stoma appliance customisation services are to be provided elsewhere than at P’s pharmacy or S’s premises, procedures must be in place to ensure co-operation with any reasonable inspection or review of the premises by the Primary Care Trust of the area where the services are provided.

Requirements applying to stoma customisation services

- 10.—**(1) This direction has effect in relation to any arrangements with a pharmacy contractor (P) or appliance contractor (S) which are made pursuant to direction 9.
- (2) The Primary Care Trust must ensure that the arrangements provide that—
 - (a) only appropriately trained and qualified persons are permitted to customise a stoma appliance;
 - (b) a record of each stoma customisation must be completed;
 - (c) each record must include the information listed in paragraph (3);

- (d) each record must be retained for a minimum period of 12 months or such longer period as the Primary Care Trust may reasonably require;
 - (e) a copy of the record must be supplied to the patient or, if requested by the patient, to the prescriber or another health care professional; and
 - (f) unless prevented from doing so by illness or other reasonable cause, P or S must give at least 3 months' notice in writing to both the Primary Care Trust and the NHS BSA in advance of ceasing to provide any stoma appliance customisation services.
- (3) Each stoma customisation record must include—
- (a) details of advice given;
 - (b) the type of stoma appliance customised;
 - (c) dimensions used in respect of the modification of parts of the appliance;
 - (d) measurements of the patient (if taken);
 - (e) dimensions of any template made or modification of any existing template;
 - (f) any referrals made to the prescriber; and
 - (g) such other details as may be specified in the arrangements made with P or S.
- (4) Stoma customisation records may be in the form of an electronic record and may be stored electronically.

Establishing and maintaining appliance use review services for specified appliances

11.—(1) Each Primary Care Trust must make arrangements for the provision of appliance use review services (“AUR services”) for persons within or outside its area by any pharmacist (“P”) or supplier of appliances (“S”)—

- (a) who is on the Primary Care Trust’s pharmaceutical list;
- (b) who supplies specified appliances in the normal course of business;
- (c) who either wishes to enter into the arrangements or is required to do so by virtue of regulation 13(3) or 14 of the Pharmaceutical Services Regulations; and
- (d) in relation to whom—
 - (i) Conditions 1, 2 and 3 are met, and
 - (ii) if services are to be provided at a pharmacy or at the premises of a supplier of appliances, Condition 4 is also met.

(2) The underlying purpose of an AUR service is, with a patient’s agreement, to improve the patient’s knowledge and use of any specified appliance by, in particular—

- (a) establishing the way the patient uses the specified appliance and the patient’s experience of such use;
- (b) identifying, discussing and assisting in the resolution of poor or ineffective use of the specified appliance by the patient;
- (c) advising the patient on the safe and appropriate storage of the specified appliance; and
- (d) advising the patient on the safe and proper disposal of specified appliances that are used or unwanted,

and an AUR service may be provided either when a pharmacist or specialist nurse visits a patient at home or when a patient visits a pharmacy or visits the premises of a supplier of appliances.

(3) Condition 1 is that, before any arrangements are entered into, the Primary Care Trust and the NHS BSA have each been supplied with—

- (a) notice that P or S wishes to provide AUR services;
- (b) a statement of whether or not P or S proposes to provide any services to patients at home; and

- (c) unless services are to be provided solely during visits to a patient at home, a statement of each location at which services are to be provided.

(4) Condition 2 is that, before any arrangements are entered into, the Primary Care Trust has also been supplied with the following information in relation to each pharmacist or specialist nurse who, as part of the AUR services to be provided by P or S, is to review the use of specified appliances—

- (a) full name;
- (b) documentary evidence of qualifications; and
- (c) details as to competency in respect of the use of specified appliances.

(5) Condition 3 is that P or S—

- (a) is satisfactorily complying with P's obligations under Schedule 1 to the Pharmaceutical Services Regulations or S's obligations under Schedule 3 to those Regulations (as the case may be); and
- (b) has procedures in place to ensure referral of a patient to the prescriber of the appliance in any case where a matter relating to a patient's use of a specified appliance arises in the course of an AUR service but falls outside the scope of the service.

(6) Condition 4 is that, where any AUR services are to be provided at a pharmacy or at the premises of a supplier of appliances, there is a consultation area at the pharmacy or premises which—

- (a) is distinct from the general public areas;
- (b) at all times when a pharmacist or specialist nurse is reviewing the use of specified appliances, is clearly designated as an area for confidential consultation;
- (c) allows all persons taking part in the review to sit down together and talk at normal speaking volumes without being overheard by other visitors to, or staff at, the pharmacy or the premises; and
- (d) having regard to the nature of specified appliances and the underlying purpose of AUR services, is suitable for a consultation to determine how a patient uses an appliance and the extent of the patient's knowledge about it.

Requirements applying to appliance use review services

12.—(1) This direction has effect in relation to any arrangements with a pharmacy contractor (P) or supplier of appliances (S) which are made pursuant to direction 11.

(2) The Primary Care Trust must ensure that the arrangements include such provision about—

- (a) the qualifications of persons who review a patient's use of specified appliances;
- (b) the delivery of each AUR service; and
- (c) the administration of AUR services,

as is set out in the following provisions of this direction.

(3) The provision referred to in paragraph (2)(a) is that—

- (a) only a pharmacist or specialist nurse is permitted to review the use of specified appliances; and
- (b) the Primary Care Trust must be sent the following information in relation to each pharmacist or specialist nurse who, as part of the AUR services provided by P or S, reviews the use of specified appliances—
 - (i) full name,
 - (ii) documentary evidence of education, training or experience in respect of the use of specified appliances, and
 - (iii) details as appropriate of relevant clinical training and practice in respect of the use of specified appliances.

- (4) The provision referred to in paragraph (2)(b) is that—
- (a) where reasonably possible, an AUR service must be provided within 2 working days of the day on which a patient requests a review or agrees to one at the suggestion of P or S;
 - (b) the pharmacist or specialist nurse who reviews the patient’s use of a specified appliance must obtain the patient’s prior written consent to receiving the service;
 - (c) a record of each service must be completed;
 - (d) each record must include—
 - (i) the date of the review of the patient’s use of the specified appliance,
 - (ii) the name of the pharmacist or specialist nurse who carried out the review,
 - (iii) the name of the patient and the address at which the review took place,
 - (iv) the name of any other person present (and their relationship with the patient),
 - (v) the reason why a review is required,
 - (vi) the advice given to the patient, and
 - (vii) any intervention made; and
 - (e) the patient must be informed in writing that the record will be kept and that information from it will be forwarded in accordance with paragraphs (5)(a) to (d).
- (5) The provision referred to in paragraph (2)(c) is that—
- (a) a copy of each record of an AUR service must be forwarded to P or S;
 - (b) if the patient is a registered patient, the information referred to in paragraph (4)(d)(i), (ii) and (iii) must be forwarded to any provider of primary medical services with which the patient is a registered patient;
 - (c) if the patient is a registered patient and the pharmacist or specialist nurse considers it necessary for the provider of primary medical services with which the patient is registered to be aware of other information from the record, all such information must be forwarded to that provider;
 - (d) any information forwarded to any provider of primary medical services under this paragraph must be copied to any nurse employed by a Primary Care Trust who is practising with the provider and providing relevant primary medical services to the patient, if it is known that there is such a nurse;
 - (e) each record must be retained for a minimum period of 12 months or for such longer period as the Primary Care Trust may reasonably require; and
 - (f) information about the number of AUR services provided in any financial year must be submitted in accordance with any arrangements for payment of which P or S is notified.
- (6) The record of an AUR service may be in the form of an electronic record and may be stored electronically.

Maximum number of appliance use review services eligible for payment

13. The maximum number of AUR services for which a pharmacy contractor (P) or an appliance contractor (S) is eligible for payment in any financial year is not more than 1/35th of the aggregate number of specified appliances dispensed during that financial year by P or S (as the case may be).

PART 4

Enhanced services: pharmacy contractors only

Enhanced services provided by pharmacy contractors

14.—(1) Each Primary Care Trust (PCT1) is authorised to arrange for the provision of the following additional pharmaceutical services to persons within or outside its area with a pharmacy

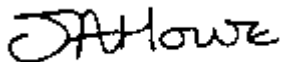
contractor (P) included in its pharmaceutical list or a pharmaceutical list of a neighbouring Primary Care Trust—

- (a) an Anticoagulant Monitoring Service, the underlying purpose of which is for P to test the patient's blood clotting time, review the results and adjust (or recommend adjustment to) the anticoagulant dose accordingly;
- (b) a Care Home Service, the underlying purpose of which is for P to provide advice and support to residents and staff in a care home relating to—
 - (i) the proper and effective ordering of drugs and appliances for the benefit of residents in the care home,
 - (ii) the clinical and cost effective use of drugs,
 - (iii) the proper and effective administration of drugs and appliances in the care home,
 - (iv) the safe and appropriate storage and handling of drugs and appliances, and
 - (v) the recording of drugs and appliances ordered, handled, administered, stored or disposed of;
- (c) a Disease Specific Medicines Management Service, the underlying purpose of which is for a registered pharmacist to advise on, support and monitor the treatment of patients with specified conditions, and where appropriate to refer the patient to another health care professional;
- (d) a Gluten Free Food Supply Service, the underlying purpose of which is for P to supply gluten free foods to patients;
- (e) an Independent Prescribing Service, the underlying purpose of which is to provide a framework within which pharmacist independent prescribers may act as such under arrangements to provide additional pharmaceutical services with PCT1 or a neighbouring Primary Care Trust;
- (f) a Home Delivery Service, the underlying purpose of which is for P to deliver to the patient's home—
 - (i) drugs, and
 - (ii) appliances other than specified appliances within the meaning of regulation 2(1) of the Pharmaceutical Services Regulations;
- (g) a Language Access Service, the underlying purpose of which is for a registered pharmacist to provide, either orally or in writing, advice and support to patients in a language understood by them relating to—
 - (i) drugs which they are using,
 - (ii) their health, and
 - (iii) general health matters relevant to them,and where appropriate referral to another health care professional;
- (h) a Medication Review Service, the underlying purpose of which is for a registered pharmacist—
 - (i) to conduct a review of the drugs used by a patient, including on the basis of information and test results included in the patient's care record held by the provider of primary medical services that holds the registered patient list on which the patient is a registered patient, with the objective of considering the continued appropriateness and effectiveness of the drugs for the patient,
 - (ii) to advise and support the patient regarding their use of drugs, including encouraging the active participation of the patient in decision making relating to their use of drugs, and
 - (iii) where appropriate, to refer the patient to another health care professional;
- (i) a Medicines Assessment and Compliance Support Service, the underlying purpose of which is for P—

- (i) to assess the knowledge of drugs, the use of drugs by and the compliance with drug regimens of vulnerable patients and patients with special needs, and
 - (ii) to offer advice, support and assistance to vulnerable patients and patients with special needs regarding the use of drugs, with a view to improving their knowledge and use of the drugs, and their compliance with drug regimens;
- (j) a Minor Ailment Scheme, the underlying purpose of which is for P to provide advice and support to eligible patients presenting with a minor ailment, and where appropriate to supply drugs to the patient for the treatment of the minor ailment;
- (k) a Needle and Syringe Exchange Service, the underlying purpose of which is for a registered pharmacist—
 - (i) to provide sterile needles, syringes and associated materials to drug misusers,
 - (ii) to receive from drug misusers used needles, syringes and associated materials, and
 - (iii) to offer advice to drug misusers and where appropriate refer them to another health care professional or a specialist drug treatment centre;
- (l) an On Demand Availability of Specialist Drugs Service, the underlying purpose of which is for P to ensure that patients or health care professionals have prompt access to specialist drugs;
- (m) Out of Hours Services, the underlying purpose of which is for P to dispense drugs and appliances in the out of hours period (whether or not for the whole of the out of hours period);
- (n) a Patient Group Direction Service, the underlying purpose of which is for P to supply or administer prescription only medicines to patients under patient group directions;
- (o) a Prescriber Support Service, the underlying purpose of which is for P to support health care professionals who prescribe drugs, and in particular to offer advice on—
 - (i) the clinical and cost effective use of drugs,
 - (ii) prescribing policies and guidelines, and
 - (iii) repeat prescribing;
- (p) a Schools Service, the underlying purpose of which is for P to provide advice and support to children and staff in schools relating to—
 - (i) the clinical and cost effective use of drugs in the school,
 - (ii) the proper and effective administration and use of drugs and appliances in the school,
 - (iii) the safe and appropriate storage and handling of drugs and appliances, and
 - (iv) the recording of drugs and appliances ordered, handled, administered, stored or disposed of;
- (q) a Screening Service, the underlying purpose of which is for a registered pharmacist—
 - (i) to identify patients at risk of developing a specified disease or condition,
 - (ii) to offer advice regarding testing for a specified disease or condition,
 - (iii) to carry out such a test with the patient's consent, and
 - (iv) to offer advice following an test and refer to another health care professional as appropriate;
- (r) a Stop Smoking Service, the underlying purpose of which is for P—
 - (i) to advise and support patients wishing to give up smoking, and
 - (ii) where appropriate, to supply appropriate drugs and aids;
- (s) a Supervised Administration Service, the underlying purpose of which is for a registered pharmacist to supervise the administration of prescribed medicines at P's pharmacy; and
- (t) a Supplementary Prescribing Service, the underlying purpose of which is for a registered pharmacist who—
 - (i) is a supplementary prescriber, and

- (ii) with a doctor or a dentist is party to a clinical management plan, to implement that plan, with the patient's agreement.
- (2) PCT1 must ensure that any such arrangements make provision for those services—
 - (a) only to be performed by appropriately trained and qualified persons; and
 - (b) only to be provided—
 - (i) in accordance with relevant national guidelines or standards,
 - (ii) from premises that are suitable for the purpose, and
 - (iii) using the appropriate or necessary equipment.

Signed by authority of the Secretary of State for Health



Jeannette Howe
 Head of Pharmacy
 Department of Health

22nd September 2011

SCHEDULE 1

Direction 5(1)(g)

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—

<i>BNF reference</i>	<i>BNF subsection descriptor</i>
BNF 10.1.1	NSAIDs
BNF 2.8.2 and 2.8.1	Anticoagulants (including low molecular weight heparin)
BNF 2.9	Antiplatelets
BNF 2.2	Diuretics

2. Patients recently (that is, within the previous 8 weeks) discharged from hospital who had changes made to the drugs they are taking while they were in hospital (it is anticipated that patients in this target group will generally be offered an MUR services consultation within 4 weeks of discharge).

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

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

SCHEDULE 2

Direction 7(1)(e)

NMS medicines

1. For the purposes of these Directions, an “NMS medicine” is a drug included in the BNF subsections referenced in the tables in this paragraph (which are headed with the conditions or therapies to which they relate)—

Asthma and Chronic Obstructive Pulmonary Disease

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

Type 2 Diabetes

<i>BNF Reference</i>	<i>BNF subsection descriptor</i>
6.1.1.1	Short acting insulins (where the community pharmacist can determine that the medicine has been newly prescribed for a patient with Type 2 diabetes)
6.1.1.2	Intermediate and long acting insulins (where the community pharmacist can determine that the medicine has been newly prescribed for a patient with Type 2 diabetes)
6.1.2	Antidiabetic drugs

Antiplatelet/Anticoagulant therapy

<i>BNF Reference</i>	<i>BNF subsection descriptor</i>
2.8.2	Oral anticoagulants
2.9	Antiplatelet drugs

Hypertension

<i>BNF Reference</i>	<i>BNF subsection descriptor</i>
2.2.1	Thiazides and related diuretics
2.4	Beta-adrenoceptor blocking drugs (where the community pharmacist can determine that the medicine has been newly prescribed for a patient with hypertension)
2.5.1	Vasodilator antihypertensive drugs
2.5.2	Centrally acting antihypertensive drugs
2.5.4	Alpha-adrenoceptor blocking drugs (where the community pharmacist can determine that the medicine has been newly prescribed for a patient with hypertension)
2.5.5	Drugs affecting the renin-angiotensin system (where the community pharmacist can determine that the medicine has been newly prescribed for a patient with hypertension)
2.6.2	Calcium-channel blockers (where the community pharmacist can determine that the medicine has been newly prescribed for a patient with hypertension)

	hypertension)
--	---------------