CONSOLIDATED DIRECTIONS

THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013

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

CONTENTS

[1] 2006 c. 41. Section 128 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), Schedule 4, paragraph 64; and section 128 has been amended by the 2012 Act, Schedule 4, paragraph 65.

PART 1

Introductory

1 Citation, commencement and application

1.—(1) These Directions may be cited as the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 and come into force on 1st April 2013.

(2) These Directions apply in relation to England.

2 Interpretation

2. In these Directions—

"the 2012 Directions" means the Pharmaceutical Services (Advanced and Enhanced Services)(England) Directions 2012[2], as in force on 31st March 2013;

"the Act" means the National Health Service Act 2006;

"appliance contractor" means a person included in a list prepared under regulation 10(2)(b) of the Pharmaceutical Services Regulations (pharmaceutical lists and EPS lists);

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

[2] Signed on 20th July 2012.

"BNF" means the current edition of British National Formulary, which is published jointly by the Royal Pharmaceutical Society and the British Medical Association[3];

"care home" means a care home within the meaning of the Care Standards Act 2000[4] in respect of which an organisation is registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008[5] (the Care Quality Commission – registration in respect of the provision of health or social care) in respect of a regulated activity (within the meaning of that Part) carried on in the home;(E)

"clinical management plan" has the same meaning as in the Human Medicines Regulations 2012[6];

""CPSIVAS" means the service specification for the CPSIVAS, produced by the NHSCB, which has the publication date of August 2017;H

" "CPSIVAS service specification" means the service specification for the CPSIVAS, produced by the NHSCB, which has the publication date of 20 August 2018[7]

"Drug Tariff" has the meaning given in regulation 89(1) of the Pharmaceutical Services;

Regulations (the Drug Tariff and section 164: general provisions);

"drugs" includes medicines;

""EPS" means the Electronic Prescription Service which is managed by NHS Digital;(G)

"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, other than a social worker, 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[8] (the Council for Healthcare Regulatory Excellence);

""IUC CAS" means an Integrated Urgent Care Clinical Assessment Service, which is such a service for the purposes of the "Integrated Urgent Care Specification" published by the NHSCB on 25th August 2017[9];

[3] The Formulary is available at www.bnf.org.
[4] 2000 c. 14 See section 3 of that Act which defines what a care home is for the purpose of that Act.
[5] 2008 c.14
[6] S.I. 2012/1916.
[7] NHS England Publications gateway reference 08291
[8] 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.
[9] NHS England Publications Gateway Reference number: 07092

"listed chemist premises" has the same meaning as in the Pharmaceutical Services Regulations;

"National PGD" means the Patient Group Direction authorised by the NHSCB in respect of the administration of inactivated influenza vaccine to adults in accordance with the CPSIVAS and national influenza immunisation programme, which is valid from 1st September 2018 and has the published expiry date of 31st March 2019(**c**) (and which may be revised from time to time) [I]

"New Medicine Service" is to be construed in accordance with direction 6(1) and (2);
"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 NHSCB (or, pending the first such approval by the NHSCB, by the Secretary of State)[10];

"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[11];

"NHSCB" means the National Health Service Commissioning Board;

"NHS prescription" means a prescription that is an electronic prescription form, an electronic repeatable prescription, a non-electronic prescription form or a non electronic repeatable prescription for the purposes of the Pharmaceutical Services Regulations;[12(B)]

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

""NHS 111 service" means the non-emergency, 24 hour medical helpline service of that name, supported by the NHSCB, which is intended for urgent but not life threatening health issues; [(G)]

NHS Digital" means the Health and Social Care Information Centre established under section 252 of the Health and Social Care Act 2012 [13] (the Health and Social Care Information Centre); [(G)]

""NHSmail" means the secure e-mail service of that name for the sharing of patient identifiable and patient sensitive information, for which NHS Digital is responsible; [(G)]

""NUMSAS" means the NHS Urgent Medicine Supply Advanced Service pilot scheme, described in direction 7C(2); [(G)]

" "NUMSAS service specification" means the service specification for the NUMSAS, produced by the NHSCB, which has the publication date of November 2016[14];[(G)]

"out of hours period" means, in relation to pharmacy premises, the periods of time that are not part of the hours during which the pharmacy premises must be open by virtue of paragraph 23(1) of Schedule 4 to the Pharmaceutical Services Regulations[15] (terms of

[10] The competency framework in place on 1st April 2013 is the one published by the Department of Health on its website, https://www.gov.uk/government/organisations/department-of-health.
[11] S.I. 2005/2414.
[12] These are the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349)
[13] The Health and Social Care Information Centre is now known as NHS Digital
[14] NHS England Publications gateway reference 06119.
[15] Paragraph 22 has been amended by S.I. 2006/3373 and 2009/2205.

service of NHS pharmacists – pharmacy opening hours: general) (these hours are referred to in those Regulations as core opening hours);

"the Pharmaceutical Services Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013[16];

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

"pharmacy contractor" means a person included in a list prepared under regulation 10(2)(a) of the Pharmaceutical Services Regulations;

"pharmacy premises" has the same meaning as in the Pharmaceutical Services Regulations;

"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 Subcontracting) Regulations 2004[17];

"relevant NHS BSA online gateway" means the service provided for on the NHS BSA website[18] which allows pharmacy contractors to submit online the information to in directions 7A(3) and 7B(13)[(E)];

"relevant Primary Care Trust", in relation to a period before 1st April 2013, means the Primary Care Trust that entered into the arrangements with the contractor that are continuing, pursuant to these Directions, with the NHSCB (where such arrangements are continuing by virtue of a transfer scheme);

"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[19] (establishment and maintenance of register); and

(b) employed or engaged by any pharmacy contractor or appliance contractor 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;

[16] S.I. 2013/349.
[17] S.I. 2004/906; see regulation 2(2) of those Regulations.
[18] The website address is www.nhsbsa.nhs.uk
[19] S.I. 2002/253

(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;

"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;

"transfer scheme" means a property transfer scheme under section 300 of the Health and Social Care Act 2012 (transfer schemes) that transfers the rights and liabilities of a Primary Care Trust under arrangements for the provision of pharmaceutical services to other persons.

"working day" means any day from Monday to Friday except Good Friday, Christmas Day or any day that is specified or proclaimed as a bank holiday in England pursuant to section 1 of the Banking and Financial Dealings Act 1971[20] (bank holidays)[(E)].

3 Revocation and saving

3.—(1) The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2012[21] are revoked.

(2) Notwithstanding the revocation in paragraph (1)—

(a) the 2012 Directions continue to have effect for the purposes of the resolution, in accordance with paragraph 13 of Schedule 9 to the Pharmaceutical Services Regulations (transitional provisions – service provision issues: NHS chemists), of any matter relating to compliance with the terms of service of NHS chemists included in the 2012 Directions which is outstanding on 1st April 2013; and

(b) for these purposes, the continuity principles (as defined in paragraph 1(8) of Schedule 9 to the Pharmaceutical Services Regulations (transitional provisions – the continuity principles)) apply to the 2012 Directions as if those Directions were provisions of the National Health Service (Pharmaceutical Services) Regulations 2012[22], as in force on 31st March 2013, for the purposes of paragraph 1 of Schedule 9 to the Pharmaceutical Services Regulations.

PART 2

Advanced services: pharmacy contractors only

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

4.—(1) The NHSCB must make arrangements for the provision of medicines use review and prescription intervention services ("MUR services") with any pharmacy contractor (P) who—

(a) meets the conditions set out in paragraphs (3) to (5); and

[20] 1971 c.80

[21] Signed on 20th July 2012.

[22] S.I. 2012/1909. These Regulations, and the amendments to them, were revoked by S.I. 2013/349.

(b) wishes to enter into such arrangements or is required to do so by virtue of regulation 66 of the Pharmaceutical Services Regulations (conditions relating to providing directed services).

(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 4 to the Pharmaceutical Services Regulations (terms of service of NHS pharmacists) 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

(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 NHSCB (or supplied them to the relevant Primary Care Trust before 1st April 2013) 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 premises, which is—

(i) clearly designated as an area for confidential consultations,

(ii) distinct from the general public areas of the pharmacy premises, 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 premises are closed to other members of the public;

(b) an area for confidential consultations which is not at P's pharmacy premises, 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 NHSCB (or before 1st April 2013 the relevant 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 NHSCB 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 NHSCB (or before 1st April 2013 the relevant 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 NHSCB (or before 1st April 2013 the relevant Primary Care Trust) may have specified (which the NHSCB 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 NHSCB to do so on that particular occasion.

5 MUR services: ongoing conditions of arrangements

5.—(1) The NHSCB must ensure that arrangements pursuant to direction 4(1) with a pharmacy contractor (P) provide that—

(a) only a registered pharmacist with an MUR certificate, a copy of which has been supplied to the NHSCB (or before 1st April 2013 the relevant 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 NHSCB's approval is required by virtue of direction 4(5)(b) or (c), if the necessary approval has been given by the NHSCB (or, in

the case of approvals under direction 4(5)(b) or (c)(ii), before 1st April 2013 by the relevant 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 NHSCB 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 premises 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) at least 70%[23(D)] of the MUR services consultations carried out by P at or from pharmacy premises 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 NHSCB);

(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 NHSCB or the Secretary of State, on request, in the manner approved for this purpose, and for the purposes approved, by the NHSCB;

(k) P ensures that where—

[23] Amendment comes into effect 1 April 2015

(i) MUR services are provided to a patient by or on behalf of P, and

(ii) a registered pharmacist providing those services is of the opinion that it is appropriate to provide feedback about the consultation to any provider of primary medical services of which that patient is a registered patient,

that feedback is provided on the approved form or in the approved manner ("approved" for these purposes means approved by the NHSCB);

(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 NHSCB must terminate the arrangements if it is on notice that P is not, or no longer, satisfactorily complying with P's obligations under Schedule 4 to the Pharmaceutical Services Regulations (terms of service of NHS pharmacists) 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 NHSCB), 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 NHSCB (or before 1st April 2013 the relevant Primary Care Trust) in writing that P intends to start providing the MUR services; and

(b) supplied the NHSCB (or before 1st April 2013 the relevant 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) For the purposes of paragraph (1)(f)(i), a patient's circumstances are to be treated as having changed sufficiently to justify one or more further consultations if the patient—

(a) has been discharged from hospital; and

(b) has had changes made to the drugs they are taking while they were in hospital.

(5) A consultation as part of a New Medicine Service is not to be taken into account for the purposes of paragraph (1)(f)(ii) if since that consultation the patient—

(a) has been discharged from hospital; and

(b) has had changes made to the drugs they are taking while they were in hospital.

(6) A form approved by the NHSCB 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).

(7) Any approval of the Secretary of State under direction 5(1)(h), (j), (k) or (o)(i) of the 2012 Directions (MUR services: ongoing conditions of arrangements) continues in effect under the corresponding provision of paragraph (1), unless or until the approval is revoked or superseded by an approval of the NHSCB under that corresponding provision.

6 New Medicine Service: general matters and preconditions for making arrangements

6.—(1) The NHSCB must make arrangements for the provision of a New Medicine Service with any pharmacy contractor (P) 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 66 of the Pharmaceutical Services Regulations (conditions relating to providing directed services).

(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 NHSCB (or before 1st April 2013 the relevant 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 NHSCB.

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

(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 NHSCB.

(7) Condition 5 is that P has in place a standard operating procedure, at the pharmacy premises 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 premises, which is—

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

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

(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 premises are 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 premises 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 premises, and

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

(11) Any approval of the Secretary of State under direction 6(3) or (6) of the 2012 Directions (New Medicine Service: general matters and preconditions for making arrangements) continues in effect under the corresponding provision of this direction, unless or until the approval is revoked or superseded by an approval of the NHSCB under that corresponding provision.

7 New Medicine Service: ongoing conditions of arrangements

7.—(1) The NHSCB must ensure that arrangements pursuant to direction 6(1) with a pharmacy contractor (P) 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 premises, 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 premises, 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 premises, 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 premises 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) for the medical condition or therapy in relation to which the NMS medicine is listed in Schedule 2, and—

(i) the prescription is on a prescription form (within the meaning given in the Pharmaceutical Services Regulations[24]) 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 premises or, provided that the registered pharmacist is at P's pharmacy premises 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

[24] See regulation 2(1) of those Regulations.

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, 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 NHSCB), 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

(iii) 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 4 to the Pharmaceutical Services Regulations (terms of service of NHS pharmacists – essential services);

(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 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 NHSCB) 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 4 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 NHSCB) 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 4 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 NHSCB must terminate the arrangements if it is on notice that P is not, or no longer, satisfactorily complying with P's obligations under Schedule 4 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 NHSCB);

(m) P provides information from those records to the NHSCB or the Secretary of State, on request, in the manner approved for this purpose, and for the purposes approved, by the NHSCB; 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.

(3) Any approval of the Secretary of State under direction 7(1)(f)(iii)(aa), (h)(iv)(bb), (j)(iii), (l) or (m) of the 2012 Directions (New Medicine Service: ongoing conditions of arrangements) continues in effect under the corresponding provision of paragraph (1), unless or until the approval is revoked or superseded by an approval of the NHSCB under that corresponding provision.

Community Pharmacy Seasonal Influenza Vaccination Advanced Service: general matters and preconditions to making arrangements

7A.—(1) Until the end of 31st March 2019, the NHSCB must make arrangements for the provision of a service as part of the CPSIVAS with any pharmacy contractor (P) who—

(a) meets the requirements set out in paragraphs (3) to (8); and

(b) wishes to enter into such arrangements or is required to do so by virtue of regulation 66 of the Pharmaceutical Services Regulations (conditions relating to providing directed services).

(2) The underlying purpose of the CPSIVAS is to enable pharmacy contractors to participate in arrangements for the administration of inactivated influenza vaccine to patients in accordance with the National PGD, as part of the NHSCB, Public Health England and Department of Health and Social Care's annual flu programme(**a**).

(3) P must be satisfactorily complying with P's obligations under Schedule 4 to the Pharmaceutical Services Regulations (Terms of service of NHS pharmacists) in respect of the provision of essential services and an acceptable system of clinical governance.

(4) Any registered pharmacist who is to be involved in the administration of vaccines as part of the service (including locums) —

(a) must have been appropriately trained and be competent to do so, having regard to the requirements of the National PGD and the CPSIVAS service specification (including the relevant requirements of the National Minimum Standards(**b**) referred to in paragraph 4.6 of that specification); and

(b) must have completed the relevant Centre for Pharmacy Postgraduate Education declaration of competence(**c**), copies of which must be kept at P's pharmacy premises.

(5) Pharmacy staff at pharmacy premises at or from which the service is to be provided, if there is any role that they may be asked to perform as part of the service, must have been appropriately trained, having regard to requirements of the National PGD and the CPSIVAS service specification.

(6) P must have in place at the pharmacy premises at or from which the service is to be provided appropriate standard operating procedures for the service, having regard to the requirements of the National PGD and the CPSIVAS service specification, about which staff (if there is any role that they may be asked to perform as part of the service) have received appropriate training and which include procedures in respect of—

(a) cold chain integrity;

(b) needle stick injuries;

(c) advice to staff involved in the service in respect of vaccination against Hepatitis B;

(d) the identification and management of adverse reactions;

(e) the handling, removal and safe disposal of any clinical waste related to the provision of the service (whether the service is provided at the pharmacy premises or elsewhere); and

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(**a**) Available at www.gov.uk/government/collections/annual-flu-programme.

(**b**) These are available at www.gov.uk/government/publications/immunisation-training-national-minimum-standards.

(**c**) This is available on the CPPE website, www.cppe.ac.uk.

(f) if vaccines are to be administered at a care home, or at a patient's home, performing that activity away from the pharmacy premises.

(7) If P is intending to administer vaccines at a care home or a patient's home as part of the CPSIVAS, P must notify the NHSCB before the first occasion on which P intends to do so in the manner provided for in the CPSIVAS service specification.

(8) P must be able to provide the services which are part of the CPSIVAS at an acceptable location, and for these purposes "acceptable location" means—

(a) a room for confidential consultations at P's pharmacy premises which meets the requirements for such a room in the CPSIVAS service specification;

(b) if, following notification to the NHSCB, P is to provide services as part of the CPSIVAS at a care home, a room at that care home which meets the requirements for such a room in the CPSIVAS service specification; or

(c) if, following notification to the NHSCB, P is to provide services as part of the CPSIVAS at a patient's home, a location in the patient's home that P considers suitable having regard to the standard operating procedures mentioned in paragraph (6).

Community Pharmacy Seasonal Influenza Vaccination Advanced Service: ongoing conditions of arrangements

7B.—(1) The NHSCB must ensure that arrangements pursuant to direction 7A(1) with a pharmacy contractor (P) include terms equivalent to the requirements set out in this direction.

(2) Inactivated influenza vaccines must only be administered under the arrangements in accordance with the National PGD, and this includes the requirements of the National PGD before and after administration of a vaccine.

(3) The only inactivated influenza vaccines to be administered under the arrangements must be those listed in the NHSCB, Public Health England and Department of Health and Social Care's annual flu programme(**a**).

(4) P must have in place and keep under review at the pharmacy premises at or from which the service is to be provided appropriate standard operating procedures for the service, as described in direction 7A(6), about which staff (if there is any role that they may be asked to perform as part of the service) have received appropriate training.

(5) Vaccines must only be administered under the arrangements by a registered pharmacist, and that registered pharmacist (including if he or she is a locum)—

(a) must have been appropriately trained and be competent to do so, having regard to the requirements of the National PGD and the CPSIVAS service specification (including the relevant requirements of the National Minimum Standards(**b**) referred to in paragraph 4.6 of that specification);

(b) must have completed the relevant Centre for Pharmacy Postgraduate Education declaration of competence(**c**), copies of which must be kept at P's pharmacy premises;

(c) must be authorised by name under the National PGD before working to it; and

(d) must adhere to—

(i) the National PGD,

(ii) the relevant requirements of the publication known as the Green Book(**d**), and,

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(**a**) Available at www.gov.uk/government/collections/annual-flu-programme.
(**b**) These are available at www.gov.uk/goverment/publications/immunisation-training-national minimum-standards.
(**c**) Available at www/cppe.ac.uk/services/docs/commissioners.
(**d**) Available at www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book.

(ii) as appropriate, to the standard operating procedures referred to in paragraph (4).

(6) P must only provide the service at an acceptable location, and for these purposes, "acceptable location" has the same meaning as in direction 7A(8).

(7) In respect of the first occasion on which P intends to administer vaccines at a care home or a patient's home as part of the CPSIVAS, P must notify the NHSCB of their intention to do so in the manner provided for in the CPSIVAS service specification.

(8) In respect of each occasion on which P intends to administer vaccines at a care home or a patient's home as part of the CPSIVAS (apart from sub-paragraph (a), which only applies where patients are being vaccinated in care homes)—

(a) P must ensure that each patient's general practitioner is made aware in advance of the vaccination that the patient will be vaccinated;

(b) P must ensure that appropriate arrangements are in place at the care home or the patient's home (having regard to the standard operating procedures mentioned in direction 7A(6)) for the handling, removal and safe disposal of any clinical waste related to the provision of the service;

(c) where vaccinations are administered at—

(i) a care home, P must ensure that vaccinations are only administered in a room which meets the requirements for such a room in the CPSIVAS service specification, or

(ii) a patient's home, P must ensure that vaccinations are only administered in a location which P considers suitable having regard to the standard operating procedures referred to in paragraph (4); and

(d) P must ensure that appropriate infection control is available at the care home or at the patient's home.

(9) P must ensure, in so far as is practicable, that services which are part of the arrangements are available and on offer at P's pharmacy premises throughout its core opening hours and supplementary opening hours (as defined in the Pharmaceutical Services Regulations(**a**)).

(10) P must ensure the service is accessible, appropriate and sensitive to the needs of all service users, and that no eligible patient is excluded or experiences particular difficulty in accessing or using the service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age (subject to the requirements of the National PGD).

(11) P must ensure the patient's consent to the administration of the vaccine is recorded using the consent form in the CPSIVAS service specification, and information in the form must be shared on request with the NHSCB, where it is needed for assurance and post payment verification.

(12) P must ensure that each patient vaccinated under the arrangements, (or where appropriate his or her carer) must be asked to complete the patient questionnaire in the CPSIVAS service specification, and thereafter P must process the information contained in any completed patient questionnaires in the manner requested by the NHSCB.

(13) As regards each patient vaccinated under the arrangements who is registered with a general practitioner, P must ensure that the patient's general practitioner is notified, using the form for this purpose in the CPSIVAS service specification, in the manner provided for in that service specification.

(14) If —

(a) a patient vaccinated under the arrangements presents with an adverse drug reaction which is or may be linked to that vaccination; and

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(**a**) *See* regulation 2(1) of those Regulations for the relevant definitions.

(b) a pharmacist who is P or who is employed or engaged by P believes the adverse reaction is of clinical significance,

P or a person employed or engaged by P must ensure that, having managed the patient's condition appropriately, the patient's general practitioner and where appropriate the Medicines and Healthcare products Regulatory Agency (under the Yellow Card Scheme) are notified as soon as possible, in the manner provided for in the National PGD and the CPSIVAS service specification.

(15) P must keep a record of all patients receiving treatment under the arrangements—

(a) in the manner required and for the purposes specified in the National PGD and the CPSIVAS service specification, including the requirements relating to signature and dating by the immuniser and, in the case of electronic records, password protection; and

(b) for the purposes specified in the National PGD and the CPSIVAS service specification.

NHSCB must terminate any arrangements that are entered into or still in force on 31st March 2019 with effect from the end of 31st March 2019.

NHS Urgent Medicine Supply Advanced Service pilot scheme: general matters and preconditions to making arrangements

7C.—(1) Until the end of March 2019[25], the NHSCB must make arrangements for the provision of a service as part of the NUMSAS with any pharmacy contractor (P) who—

(a) meets the requirements set out in paragraphs (3) to (8); and

(b) wishes to enter into such arrangements or is required to do so by virtue of regulation 66 of the Pharmaceutical Services Regulations (conditions relating to providing directed services).

(2) The underlying purposes of the NUMSAS are—

(a) to enable pharmacy contractors, in cases of urgency, to supply a drug or appliance under arrangements for the provision of NHS pharmaceutical services to a patient referred to them via the NHS 111 service or an IUC CAS[26] who has previously been prescribed the drug or appliance in an NHS prescription but it is impractical for the patient to obtain an NHS prescription for the drug or appliance without undue delay; and

(b) to support patients in understanding the importance of not running out of medicines or appliances with a view to preventing the future need for emergency supplies.

(3) P must notify the NHSCB via the NHS BSA website[27] of P's intention to provide services as part of the NUMSAS, prior to doing so.

(4) P must be satisfactorily complying with P's obligations under Schedule 4 to the Pharmaceutical Services Regulations (Terms of service of NHS pharmacists) in respect of the provision of essential services and an acceptable system of clinical governance.

(5) P must have in place at the pharmacy premises at or from which the service is to be provided a business continuity plan and standard operating procedures, both of which are to cover provision of the service (having been amended to do so) as appropriate, having regard to the requirements of the NUMSAS service specification.

(6) Pharmacy staff at pharmacy premises at or from which the service is to be provided, if there is any role that they may be asked to perform as part of the service,

[25] Amended by Paragraph 4 of The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No.2) Directions 2018

[26] Inserted by Paragraph 3 (b) of The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2018

[27] This is www.nhsbsa.nhs.uk.

must have been appropriately trained and must have appropriate knowledge (including of the relevant provisions of the business continuity plan and the standard operating procedures) and skills, having regard to requirements of the NUMSAS service specification.

(7) P must be able to provide services which are part of the NUMSAS in a room for confidential consultations at P's pharmacy premises which meets the requirements for such a room in the NUMSAS service specification.

(8) Pharmacy professionals at the pharmacy premises at or from which the service is to be provided must have access to and be able to use—

(a) the EPS, including the EPS tracker system;

(b) NHS summary care records, if P has access to these;

(c) NHSmail; and

(d) if another electronic messaging system is used by the NHS 111 service or an IUC CAS[28] within their locality for referrals as part of the NUMSAS, that system.

NHS Urgent Medicine Supply Advanced Service pilot scheme: ongoing conditions of arrangements

7D.—(1) The NHSCB must ensure that arrangements pursuant to direction 7C(1) with a pharmacy contractor (P) include terms equivalent to the requirements set out in this direction.

(2) P must comply with the requirements of the NUMSAS service specification, in particular in respect of—

(a) the handling of referrals via the NHS 111 service or an IUC CAS, including in respect of checking to see if referrals have been made and actions to be taken before the pharmacy premises close;

(b) dealing with circumstances where a patient requests the service but has not been referred via the NHS 111 service or an IUC CAS;

(c) the conduct of the initial telephone contact between P and the patient, including in respect of the obtaining of patient consent, as appropriate;

(d) access to and making appropriate use of NHS summary care records during the telephone conversation with a patient, or if not done then, during the physical consultation with the patient, in the manner required by paragraphs 3.2.4 and 3.3.2 of the NUMAS service specification, including recording the reason for not doing so, and the EPS;

(e) access to and making appropriate use of NHSmail, and if another electronic messaging system is used by the NHS 111 service or an IUC CAS within their locality for referrals as part of the NUMSAS, of that system;

(f) the conduct of face to face consultations;

(g) dealing with the circumstances where it is not appropriate to make an emergency supply (for example where the prescription is available via the EPS or the relevant requirements of the Human Medicines Regulations 2012[29] are not met);

(h) dealing with emergency supplies, where it is appropriate for an emergency supply to be made;

[28] Inserted by Paragraph 3 (c) of The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2018

[29] S.I. 2012/1916.

(i) dealing with onward referrals, in the circumstances where these are provided for in the service specification;

(j) ensuring that the patient and, if there is contact with a representative of the patient, the patient's representative, are given appropriate information and advice (in particular, to support patients in understanding the importance of not running out of medicines or appliances), and appropriate records are made of that information and advice, as provided for in the service specification;

(k) ensuring that the documentation that needs to be duly completed for P to be paid the due amount for the service is duly completed;

(l) ensuring that the patient or a representative of the patient—

(i) duly completes the documentation required to ensure that NHS prescription charges are paid or exemptions are claimed correctly, and that the required checks are made of evidence of entitlement to exemptions, and

(ii) is asked to complete the patient experience survey relating to the service;

(m) collecting NHS prescription charges, where these are payable;

(n) ensuring there is appropriate feedback from P to the NHS 111 service or an IUC CAS;

(o) ensuring there is appropriate notification of the patient's GP practice of the supply of any drug or appliance as part of the service, as provided for in the service specification; and

(p) managing all records created or amended as part of the service as provided for in the service specification.

(3) P must ensure that pharmacy staff at pharmacy premises at or from which the service is to be provided, if there is any role that they may be asked to perform as part of the service, are appropriately trained and have appropriate knowledge (including of the relevant provisions of the business continuity plan and the standard operating procedures) and skills, having regard to requirements of the NUMSAS service specification.

(4) P must have in place and keep under review at the pharmacy premises at or from which the service is provided a business continuity plan and standard operating procedures, both of which are to cover provision of the service (having been amended to do so) as appropriate, having regard to the requirements of the NUMSAS service specification.

(5) P must where appropriate hold face to face consultations in the room at P's premises for confidential consultations which meets the requirements for such a room in the NUMSAS service specification, as mentioned in direction 7C(7).

(6) P must ensure, in so far as is practicable, that services which are part of the NUMSAS are available and on offer at P's pharmacy premises at the times during its core opening hours and supplementary opening hours (as defined in the Pharmaceutical Services Regulations[30] when, having regard to the NUMSAS service specification, the services are to be provided.

(7) P must ensure that services which are part of the NUMSAS are accessible, appropriate and sensitive to the needs of all service users, and that no eligible patient is excluded or experiences particular difficulty in accessing or using the service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.

[30] *See* regulation 2(1) of those Regulations.

(8) P must not actively promote services which are part of the NUMSAS directly to the public.

(9) P must participate in any local audit of integrated urgent care service provision provided for in the NUMSAS service specification.

(10) P must participate in any evaluation of the pilot scheme provided for in the NUMSAS service specification.

(11) If P is to terminate P's participation in the NUMSAS, P must notify the NHSCB via the NHS BSA website as provided for in the NUMSAS service specification.

(12) The NHSCB must terminate any arrangements that are entered into or still in force on 31st March 2019 with effect from the end of 31st March 2019

8 Duration of New Medicine Service

8. Revoked by [C]

PART 3

Advanced services: appliances

9 Establishing and maintaining stoma appliance customisation services

9.—(1) The NHSCB must make arrangements for the provision of stoma appliance customisation services by any pharmacy contractor (P) or appliance contractor (S)—

(a) who supplies stoma appliances listed in Part IXC of the Drug Tariff in the normal course of business;

(b) who either wishes to enter into the arrangements or is required to do so by virtue of regulation 66 of the Pharmaceutical Services Regulations (conditions relating to providing directed services); and

(c) 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 or S's listed chemist 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 NHSCB (or before 1st April 2013 the relevant 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 4 to the Pharmaceutical Services Regulations (terms of services of NHS pharmacists) or S's

obligations under Schedule 5 to those Regulations (terms of service of NHS appliance contractors), 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 or S's listed chemist 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 or S's listed chemist 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 or S's listed chemist premises, procedures must be in place to ensure co-operation with any reasonable inspection or review of the premises by the NHSCB.

10 Requirements applying to stoma appliance 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 NHSCB 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 NHSCB 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 NHSCB (or if it was before 1st April 2013, the relevant 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.

11 Establishing and maintaining appliance use review services for specified appliances

11.—(1) The NHSCB must make arrangements for the provision of appliance use review services ("AUR services") by any pharmacist ("P") or supplier of appliances ("S")—

(a) who supplies specified appliances in the normal course of business;

(b) who either wishes to enter into the arrangements or is required to do so by virtue of regulation 66 of the Pharmaceutical Services Regulations (conditions relating to providing directed services); and

(c) in relation to whom—

(i) Conditions 1, 2 and 3 are met, and

(ii) if services are to be provided at listed chemist premises, 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 listed chemist premises.

(3) Condition 1 is that, before any arrangements are entered into, the NHSCB (or before 1st April 2013 the relevant 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 (which must be listed chemist premises) at which services are to be provided.

(4) Condition 2 is that, before any arrangements are entered into, the NHSCB (or before 1st April 2013 the relevant 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 4 to the Pharmaceutical Services Regulations (terms of service of NHS pharmacists) or S's obligations under Schedule 5 to those Regulations (terms of service of NHS appliance contractors), 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 listed chemist premises, there is a consultation area at the 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 overhead by other visitors to, or staff at, 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.

12 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 NHSCB 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 NHSCB must be sent (unless before 1st April 2013 the relevant Primary Care Trust was 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); and

(f) a patient must not be refused delivery of an AUR service by reason solely of the patient's location if P or S would, in the normal course of business, dispense the related specified appliance to that location.

(5) The provision referred to in paragraph (2)(c) is that—

(a) a copy of each record of an AUR service must be provided by the pharmacist or specialist nurse 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 who is—

(i) employed or engaged by a provider, under arrangements with a clinical commissioning group, of services as part of the health service, and

(ii) providing relevant health care 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 NHSCB 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.

13 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

14 Enhanced services provided by pharmacy contractors

14.—(1) The NHSCB is authorised to arrange for the provision of the following additional pharmaceutical services with a pharmacy contractor (P)—

(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;

(aa) an Antiviral Collection Service, the underlying purpose of which is for P to supply antiviral medicines, in accordance with regulation 247 of the Human Medicines Regulations 2012[31] (exemption for supply in the event or in anticipation of pandemic disease), to patients for treatment or prophylaxis;[(D)]

(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 the NHSCB;

(f) a Home Delivery Service, the underlying purpose of which is for P to deliver to the patient's home—

(i) drugs, and

[31] Amended by S.I. 2013/235

(ii) appliances other than specified appliances;

(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 premises;

(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; and

(u) an Emergency Supply Service, the underlying purpose of which is to ensure that, in cases of urgency, patients, at their request, have prompt access to drugs or appliances—

(i) which have previously been prescribed for them in an NHS prescription but for which they do not have an NHS prescription, and

(ii) where, in the case of prescription only medicines, the requirements of regulation 225(1) of the Human Medicines Regulations 2012 (emergency sale etc by pharmacist: at patient's request) are satisfied.[(B)]

(2) The NHSCB 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

12th March 2013 Department of Health

SCHEDULE 1 - 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 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—

BNF Reference	*BNF subsection descriptor*
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

4. Patients who are regularly being prescribed four or more medicines, at least one of which is a medicine which is included in the BNF chapter and subsections referenced in the table in this paragraph[(D)]—

BNF Reference	*BNF subsection descriptor*
Chapter 2	Cardiovascular System
Sub Chapter 6.1	Drugs used in Diabetes
Sub Chapter 6.2	Thyroid and Anti Thyroid Drugs

SCHEDULE 2 - 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

BNF Reference	*BNF subsection descriptor*
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

BNF Reference	*BNF subsection descriptor*
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

BNF Reference	*BNF subsection descriptor*
2.8.2	Oral anticoagulants
2.9	Antiplatelet drugs

Hypertension

BNF Reference	*BNF subsection descriptor*
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)

Subsequent Secretary of State amendments to Directions used in this consolidation

Code	Title	Effective Date
A	The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2013	29 September 2013
B	The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2013	07 December 2013
C	The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2014	13 March 2014
D	The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No.2) Directions 2014	01 January 2015 (except for that amending Direction 5 which came into force on 01 April 2015)
E	The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2015	16 September 2015
F	The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2016	01 September 2016
G	The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No.2) Directions 2016	01 December 2016
H	The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2017	01 September 2017
I	The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2018	30 March 2018
J	The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No.2) Directions 2018	01 September 2018