
DIRECTIONS

THE NATIONAL HEALTH SERVICE ACT 2006

The Primary Medical Services (Directed Enhanced Services) (England) (Amendment) Directions 2011

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

Citation, commencement and application

1.—(1) These Directions may be cited as the Primary Medical Services (Directed Enhanced Services) (England) (Amendment) Directions 2011 and shall come into force on 1st April 2011.

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

Amendment to the Primary Medical Services (Directed Enhanced Services) (England) Directions 2010

2. The Primary Medical Services (Directed Enhanced Services) (England) Directions 2010 signed on 3rd March 2010(b) are amended in accordance with directions 3 to 10.

Amendment to direction 2

3. In direction 2 (interpretation), omit the definition of “clinical session”.

Amendment to direction 3

4.—(1) Direction 3 (establishment etc. of directed enhanced services schemes) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), for “general practitioner”, substitute “health care professional”;

(b) omit sub-paragraph (c);

(c) at the end of sub-paragraph (h), omit “and”;

(d) at the end of sub-paragraph (i), insert “and”;

(e) after sub-paragraph (i), insert—

“(j) a Patient Participation Scheme, the underlying purpose of which is to encourage contractors—

(i) to obtain, through the carrying out of a local practice survey, the views of their registered patients in respect of the provision of primary medical services by, and manner in which, primary medical services are provided by the contractor; and

(ii) to identify from the local practice survey those primary medical services, the provision of which by, and manner in which they are provided by, the

(a) 2006 c.41. Sections 272 has been amended sections 18 and 13 of, and paragraphs 6 and 10 of Schedule 1 to, the Health Act 2009 (c.21), and section 273 has been amended by S.I. 2010/22.

(b) These Directions are published on www.dh.gov.uk.

contractor needs to be improved and, where it is appropriate, to take reasonable steps to improve such services”.

Substitution of direction 4

5. For direction 4 (extended hours access scheme), substitute—

“4.—(1) As part of its Extended Hours Access Scheme, each Primary Care Trust must before 30th April 2011 and subject to paragraphs (2) and (5), offer to—

- (a) each GMS contractor in its area who has entered into a contract which subsists on 1st April 2011; and
- (b) each PMS contractor in its area for which it holds a list of registered patients and who has entered into an agreement which subsists on 1st April 2011,

the opportunity to enter into arrangements under the Scheme in respect of the twelve month period ending on 31st March 2012.

(2) Unless paragraph (3) applies, a Primary Care Trust must, as far as is reasonably practicable, agree proposals to enter into arrangements under the Scheme and enter into such arrangements before 1st July 2011.

(3) A Primary Care Trust is required to enter into, as part of its Extended Hours Access Scheme, such arrangements after 30th June 2011 only where—

- (a) the contractor—
 - (i) has not provided the Primary Care Trust with its proposals to enter into arrangements before 1st July 2011, and
 - (ii) on the 30th June 2011, 28 days have not lapsed since the offer to enter into arrangements was made by the Primary Care Trust,

in which case, the Primary Care Trust must consider the contractor’s proposals in accordance with paragraph (4);

- (b) two or more GMS or PMS contracts (under at least one of which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) merge and—
 - (i) as a result two or more patient lists are combined, resulting in either a new GMS or PMS contract or a varied GMS or PMS contract,
 - (ii) the contractor who is a party to such a new or varied contract wishes to enter into new arrangements under paragraph (1), and
 - (iii) pending such new arrangements, the contractor provides extended hours access arrangements which are, in the opinion of the Primary Care Trust, broadly comparable to what is necessary in order to provide the minimum hours of extended access required under these Directions,

in which case the Primary Care Trust is required to enter into new arrangements under the Scheme referred to in paragraph (1) on or before the expiry of the period of 28 days beginning with the date of the merger; or

- (c) a GMS or PMS contract (under which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) splits and—
 - (i) as a result the contractor’s patient list is divided between two or more GMS or PMS contractors, resulting in either new GMS or PMS contracts or varied GMS or PMS contracts, or a combination of both, and a contractor who is a party to such a new or varied contract wishes to enter into new arrangements under paragraph (1), and
 - (ii) pending such new arrangements, the contractor provides extended hours access arrangements which are, in the opinion of the Primary Care Trust, broadly comparable to what is necessary in order to provide the minimum hours of extended access required under these Directions,

in which case the Primary Care Trust is required to enter into new arrangements under the Scheme referred to in paragraph (1) on or before the expiry of the period of 28 days beginning with the date of the split.

- (4) A Primary Care Trust must—
- (a) consider any proposals put forward by a GMS or PMS contractor which wishes to enter into arrangements under paragraphs (1) and (3) with a view to agreeing them;
 - (b) not delay any such consideration unreasonably;
 - (c) not withhold its agreement unreasonably; and
 - (d) in making a decision as to whether to agree to any proposals, have regard to any relevant local circumstances, any known patient preferences and any relevant guidance issued by the Secretary of State.
- (5) A Primary Care Trust is not required to consider and reach a decision on any proposals in accordance with paragraph (4) if the GMS or PMS contractor has failed to provide—
- (a) written proposals in response to the Primary Care Trust's offer to enter into arrangements within 28 days of that Primary Care Trust's offer; or
 - (b) any information requested by the Primary Care Trust that the Primary Care Trust reasonably requires in order to ascertain whether the proposals meet its requirements.
- (6) The arrangements that a Primary Care Trust enters into with a GMS or PMS contractor for extended hours access must be in writing and must include—
- (a) a written obligation by the contractor to implement the agreed arrangements in so far as they place obligations upon it;
 - (b) details of the arrangements the contractor proposes to make in order to enable patients to consult a health care professional, face to face, at times other than during the core hours specified in the contractor's primary medical services contract; and those arrangements must comply with the following provisions—
 - (i) the arrangements must include the provision of a clinical session or sessions, provided by a health care professional, on a regular basis each week from the contractor's practice premises which are held at times other than during the core hours specified in the contractor's primary medical services contract;
 - (ii) any clinical session or sessions provided must be in addition to the contractor's normal provision of clinical sessions during core hours;
 - (iii) the additional period of the clinical session or sessions provided must, as a minimum, equate to a period of time calculated as follows—
 - (aa) first, divide the contractor's CRP at the time the arrangements are agreed by 1000;
 - (bb) then, multiply the figure obtained from the calculation made under subparagraph (aa) by 30;
 - (cc) then, convert the figure obtained from the calculation made under subparagraph (bb) into hours and minutes, rounded to the nearest quarter hour;
 - (iv) the agreed period of time of any additional clinical session or sessions must be provided in full and may be met by a clinical session or sessions consisting of concurrent appointments which, when added together, provide the equivalent of the agreed period of time;
 - (v) any clinical session or sessions provided must be provided in continuous periods of at least 30 minutes;
 - (c) a requirement that the contractor co-operate with the Primary Care Trust in any review of the arrangements designed to establish whether the pattern of additional

hours provided under the arrangements is meeting the requirements of the contractor's registered patients;

- (d) where the contractor provides out of hours services to its patients, a requirement that the contractor will not limit access to any additional clinical session or sessions it provides under the agreement to those patients that it would in any event have been obliged to see in accordance with its obligations in providing that out of hours service;
- (e) the arrangements for the provision of information by the Primary Care Trust and by the contractor;
- (f) the arrangements for the monitoring of the arrangements by the Primary Care Trust;
- (g) the arrangements for changing the pattern of, or for cessation of, agreed extended opening times, including an agreed notice period for any such changes or cessation;
- (h) the arrangements to be made by the contractor and the Primary Care Trust for informing the contractor's patients about the additional clinical session or sessions being made available under these arrangements; and
- (i) in the case of PMS contractors, the amount of the payments to be made to the contractor for meeting its obligations under the arrangements, and in determining the appropriate level of those payments the Primary Care Trust must have regard to the amounts of payments under section 7GB of the Statement of Financial Entitlements,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the arrangements comprise part of the contractor's contract and the requirements of the arrangements are conditions of the contract.

(7) No variation of the primary medical services contract to incorporate an Extended Hours Access arrangement shall provide—

- (a) in the case of a contractor that does not provide out of hours services, that any obligation under the contract to attend on a patient outside practice premises (in accordance with terms of the contract which have effect as those specified in—
 - (i) paragraph 3 of Schedule 6 to the National Health Service (General Medical Services Contracts) Regulations 2004(a), or
 - (ii) paragraph 4 of Schedule 5 to the National Health Service (Personal Medical Services Agreements) Regulations 2004(b)),applies in respect of any additional period during which the contractor is providing services in accordance with the Extended Hours Access arrangements; or
- (b) that Saturday is to be considered a "working day" for the purposes of any calculation of a period of time required under the contract where such calculation is defined with reference to "working day".

Substitution of direction 5

6. For direction 5 (alcohol related risk reduction scheme) substitute—

“5.—(1) As part of its Alcohol Related Risk Reduction Scheme, each Primary Care Trust must before 30th April 2011 and subject to paragraph (3) offer to—

- (a) each GMS contractor in its area who has entered into a contract before 1st April 2011 and such a contract subsists on 1st April 2011; and

(a) S.I. 2004/291. There are no relevant amendments.

(b) S.I. 2004/627. There are no relevant amendments.

- (b) each PMS contractor in its area for which it holds a list of registered patients and who has entered into an agreement before 1st April 2011 and such an agreement subsists on 1st April 2011,

the opportunity to enter into arrangements under the Scheme in respect of the twelve month period ending on 31st March 2012.

(2) A Primary Care Trust must subject to paragraph (3) offer to—

- (a) each GMS contractor in its area who enters into a contract on or after 1st April 2011; and
- (b) each PMS contractor in its area for which it holds a list of registered patients and who enters into an agreement on or after 1st April 2011,

the opportunity to enter into arrangements under the Scheme referred to in paragraph (1) for the remainder of the financial year.

(3) A Primary Care Trust is required to enter into arrangements under the Scheme referred to in paragraph (1) after 31st December 2011, only where—

- (a) two or more GMS or PMS contracts (under which at least one of which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) merge and as a result two or more patient lists are combined, resulting in either a new GMS or PMS contract or a varied GMS or PMS contract, and the contractor who is a party to such a new or varied contract wishes to enter into new arrangements under the Scheme referred to in paragraph (1); or
- (b) a GMS or PMS contract (under which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) splits and as a result the contractor's patient list is divided between two or more GMS or PMS contractors, resulting in either new GMS or PMS contracts or varied GMS or PMS contracts or a combination of both and a contractor who is a party to such a new or varied contract wishes to enter into new arrangements under the Scheme referred to in paragraph (1),

in which case the Primary Care Trust is required to enter into the new arrangements under the Scheme referred to in paragraph (1), and such arrangements must commence on or before the expiry of the period of 28 days beginning with the date of the merger or the split as the case may be.

(4) A Primary Care Trust must—

- (a) consider any proposals put forward by a GMS or PMS contractor which wishes to enter into arrangements under the Scheme referred to in paragraphs (1) and (2) with a view to agreeing them;
- (b) not delay any such consideration unreasonably; and
- (c) not withhold its agreement unreasonably.

(5) A Primary Care Trust is not required to consider and reach a decision in respect of entering into any arrangements under the Scheme referred to in paragraph (1) where a GMS or PMS contractor has failed to provide written proposals in response to the Primary Care Trust's offer to enter into such arrangements within 42 days beginning with the date of the offer.

(6) The arrangements that a Primary Care Trust enters into with a GMS or PMS contractor as part of its Alcohol Related Risk Reduction Scheme must be in writing and must include—

- (a) a requirement that the contractor screen newly registered patients aged 16 and over using either one of two shortened versions of the World Health Organisation (WHO) Alcohol Use Disorders Identification Test (AUDIT) questionnaire: FAST (which has four questions) or AUDIT-C (which has three questions);
- (b) a requirement that if a patient is identified as positive using either shortened version of the AUDIT questionnaire, the remaining questions of the full ten-

question AUDIT questionnaire are to be used to determine increasing risk, higher risk or likely dependent drinking;

- (c) a requirement that if a patient is identified as drinking at increasing risk or higher risk levels, the contractor—
 - (i) deliver the recommended brief intervention specified in paragraph (7) to such patient,
 - (ii) respond to any other identified need in such patient that relates to their levels of drinking, and
 - (iii) provide any treatment that relates to the patient's levels of drinking and which may be required under the contractor's primary medical services contract;
- (d) a requirement that if a patient is identified as a dependent drinker the contractor shall offer to refer that patient to specialist services;
- (e) a requirement that the contractor make relevant entries in the patient's medical record;
- (f) a requirement that before 30th April 2012, the contractor provides the following information (in writing) in respect of the twelve month period ending on 31st March 2012—
 - (i) the number of newly registered patients aged 16 and over who have been screened by the contractor using either one of two shortened versions of the World Health Organisation (WHO) Alcohol Use Disorders Identification Test (AUDIT) questionnaire (FAST or AUDIT-C) during that period,
 - (ii) the number of newly registered patients aged 16 and over who have screened positive under either one of two shortened versions of the World Health Organisation (WHO) Alcohol Use Disorders Identification Test (AUDIT) questionnaire (FAST or AUDIT-C) during that period who then undergo a fuller assessment using the full ten-question AUDIT questionnaire to determine an increasing risk, higher risk or likely dependent drinking,
 - (iii) the number of newly registered patients who have been identified as drinking at increasing risk or higher risk levels who have during that period received a brief intervention to help them reduce their alcohol-related risk, and
 - (iv) the number of newly registered patients scoring 20 or more on the full ten-question AUDIT questionnaire who have been referred by the contractor for specialist advice for dependent drinking during that period;
- (g) details of the arrangements for the provision of information by the Primary Care Trust and by the contractor in addition to any information the contractor is required to provide in accordance with sub-paragraph (f);
- (h) details of the arrangements for the monitoring of the arrangements by the Primary Care Trust;
- (i) in the case of PMS contractors, the amount of the payments to be made to the contractor for meeting its obligations under the arrangements, and in determining the appropriate level of those payments the Primary Care Trust must have regard to the amounts of payments under section 7HB of the Statement of Financial Entitlements,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the arrangements comprise part of the contractor's contract and the requirements of the arrangements are conditions of the contract.

(7) The recommended brief intervention for use in the case of patients identified as drinking at increasing risk or higher risk levels is the basic five minutes of advice used in

the WHO clinical trial of brief intervention in primary care, using the programme modified for the UK context by the University of Newcastle – *How Much Is Too Much?(a)*.”

Omission of direction 6

7. Omit direction 6 (ethnicity and first language recording scheme).

Substitution of direction 7

8. For direction 7 (learning disabilities health check scheme), substitute—

“7.—(1) As part of its Learning Disabilities Health Check Scheme, each Primary Care Trust must before 30th April 2011 and subject to paragraph (3) offer to—

- (a) each GMS contractor in its area who has entered into a contract before 1st April 2011 and such a contract subsists on 1st April 2011; and
- (b) each PMS contractor in its area for which it holds a list of registered patients and who has entered into an agreement before 1st April 2011 and such an agreement subsists on 1st April 2011,

the opportunity to enter into arrangements under the Scheme in respect of the twelve month period ending on 31st March 2012.

- (2) A Primary Care Trust must subject to paragraph (3) offer to—

- (a) each GMS contractor in its area who enters into a contract on or after 1st April 2011; and
- (b) each PMS contractor in its area for which it holds a list of registered patients and who enters into an agreement on or after 1st April 2011,

the opportunity to enter into the arrangements under the Scheme referred to in paragraph (1) for the remainder of the financial year.

- (3) A Primary Care Trust is required to enter into an arrangement under the Scheme referred to in paragraph (1) after 31st December 2011, only where—

- (a) two or more GMS or PMS contracts (under at least one of which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) merge and as a result two or more patient lists are combined, resulting in either a new GMS or PMS contract or a varied GMS or PMS contract, and the contractor who is a party to such a new or varied contract wishes to enter into new arrangements referred to in paragraph (1); or
- (b) a GMS or PMS contract (under which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) splits and as a result the contractor’s patient list is divided between two or more GMS or PMS contractors, resulting in either new GMS or PMS contracts or varied GMS or PMS contracts, or a combination of both, and a contractor who is a party to such a new or varied contract wishes to enter into a new arrangement referred to in paragraph (1),

in which case the Primary Care Trust is required to enter into a new arrangement under the Scheme referred to in paragraph (1), and such an arrangement must commence on or before the expiry of the period of 28 days beginning with the date of the merger or the split as the case may be.

- (4) A Primary Care Trust must—

- (a) consider any proposals put forward by a GMS or PMS contractor which wishes to enter into arrangements under the Scheme referred to in paragraphs (1) and (2) with a view to agreeing them;
- (b) not delay any such consideration unreasonably; and

(a) This programme and associated audit tools can be accessed on the following website <http://www.alcohollearningcentre.org.uk/Topics/Browse/BriefAdvice/>

(c) not withhold its agreement unreasonably.

(5) A Primary Care Trust is not required to consider and reach a decision in respect of entering into any arrangement under the Scheme referred to in paragraph (1) where a GMS or PMS contractor has failed to provide written proposals in response to the Primary Care Trust's offer to enter into such arrangements within 42 days beginning with the date of the offer.

(6) The arrangement that a Primary Care Trust enters into with a GMS or PMS contractor as part of its Learning Disabilities Health Check Scheme must be in writing and must include—

- (a) a requirement that the contractor—
 - (i) set up and agree with the Primary Care Trust a “health check learning disabilities register”, or
 - (ii) in a case where the Primary Care Trust had entered into a previous scheme under Direction 7 of the Primary Medical Services (Directed Enhanced Services) (England) Directions 2008(a) or Direction 7 of these Directions as in force immediately before 1st April 2011, retain any previous health check learning disabilities register required in accordance with those Directions, the purpose of which is to identify those of its registered patients aged 18 or over with learning disabilities who are to be invited for an annual health check under the arrangement;
- (b) a requirement that in order to establish which of their registered patients should be included on the health check learning disabilities register, the contractor will liaise with the local authority social services department or departments for the area or areas from which their registered patients are drawn and establish which of their registered patients are known to the local authority social services primarily because of their learning disabilities(b);
- (c) a requirement that the contractor includes those of its registered patients identified by such liaison with the local authority or authorities in its health check learning disabilities register;
- (d) a requirement that the contractor review any learning disabilities register it has already set up under Quality and Outcomes Framework arrangements under its contract and ensure that such learning disabilities register includes all those registered patients that have been identified for inclusion in the health check learning disabilities register;
- (e) a requirement that the contractor takes reasonable steps to keep the health check learning disabilities register up to date throughout the period of the arrangement by removing and adding registered patients as appropriate;
- (f) a requirement that the contractor provides the Primary Care Trust with such information as the Primary Care Trust may reasonably require to demonstrate that it has robust systems in place to maintain such register accurately;
- (g) a requirement that the contractor will offer an annual health check to each patient on its health check learning disabilities register;
- (h) a requirement that, where the patient consents, the health check provided under the arrangement will involve any carer, support worker or other person considered appropriate by either the patient or the contractor;

(a) The Primary Medical Services (Directed Enhanced Services) (England) Directions 2008, signed on 1st September 2008 and amended by the Primary Medical Services (Directed Enhanced Services) (England) (Amendment) Directions 2009, signed on 29th January 2009. Both sets of Directions were revoked by the Primary Medical Services (Directed Enhanced Services) (England) Directions 2010.

(b) See Appendix 2 Guidance and Audit Requirements for the learning disabilities health check scheme in the Clinical Directed Enhanced Services for GMS Contracts Guidance published jointly by NHS Employers and BMA on <http://www.nhsemployers.org>.

- (i) a requirement that any health check provided under the arrangement will, as a minimum, include—
 - (i) a review of the patient’s physical and mental health that includes—
 - (aa) the provision of relevant health promotion advice,
 - (bb) a chronic illness and system enquiry,
 - (cc) a physical examination,
 - (dd) a consideration of whether the patient suffers from epilepsy,
 - (ee) a consideration of the patient’s behaviour and mental health,
 - (ff) a specific syndrome check;
 - (ii) a check on the appropriateness of any prescribed medicines;
 - (iii) a review of coordination arrangements with secondary care; and
 - (iv) where appropriate, a review of any transitional arrangements on the patient attaining the age of 18;
- (j) a requirement that in carrying out any health check provided under the arrangements the contractor will use—
 - (i) the “Cardiff” health check protocol which is available through the Royal College of General Practitioners’ website^(a), or
 - (ii) a similar protocol agreed with the Primary Care Trust;
- (k) a requirement that before undertaking any health check under the arrangement the contractor will arrange a training session, if it has not already done so, for its staff which meets the following requirements—
 - (i) the training session must be attended by such members of the contractor’s staff as are agreed between the contractor and the Primary Care Trust, which must include as a minimum—
 - (aa) the lead General Practitioner, the lead practice nurse and either the practice manager or the senior receptionist, if the contractor’s staff include staff with those designations, or
 - (bb) where the contractor’s staff does not include staff with those designations, those members of the contractor’s staff whose roles are analogous to those designations;
 - (ii) the training session must consist of a multi-professional education session approved by the Primary Care Trust; and
 - (iii) the training session must include instruction on overcoming any attitudinal barriers of the staff with a view to improving their communication with patients with learning disabilities;
- (l) a requirement that the contractor makes relevant entries in the patient’s medical record, including any refusal by a patient to take up the offer of a health check;
- (m) a requirement that before 30th April 2012 the contractor informs the Primary Care Trust (in writing) of the number of registered patients on the health check learning disabilities register who have received a health check undertaken by the contractor under the arrangement referred to in paragraph (1) in respect of the twelve month period ending on 31st March 2012;
- (n) details of the arrangements for the provision of information by the Primary Care Trust and by the contractor in addition to any information the contractor is required to provide in accordance with sub-paragraph (m);
- (o) details of the arrangements for the monitoring of the arrangements by the Primary Care Trust;

(a) The website can be found at: http://www.rcgp.org.uk/PDF/clinical_welsh_health_check_newA.pdf

- (p) in the case of PMS contractors, the amount of the payments to be made to the contractor for meeting its obligations under the arrangements and in determining the appropriate level of those payments the Primary Care Trust must have regard to the amounts of payments under section 7JB of the Statement of Financial Entitlements,
- and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the arrangements comprise part of the contractor's contract and the requirements of the arrangements are conditions of the contract.”.

Substitution of direction 8

9. For direction 8 (osteoporosis diagnosis and prevention scheme), substitute—

“8.—(1) As part of its Osteoporosis Diagnosis and Prevention Scheme, each Primary Care Trust must before 30th April 2011 and subject to paragraph (3) offer to—

- (a) each GMS contractor in its area who has entered into a contract before 1st April 2011 and such a contract subsists on 1st April 2011; and
- (b) each PMS contractor in its area for which it holds a list of registered patients and who has entered into an agreement before 1st April 2011 and such an agreement subsists on 1st April 2011,

the opportunity to enter into arrangements under the Scheme in respect of the twelve month period ending on 31st March 2012.

(2) A Primary Care Trust must subject to paragraph (3) offer to—

- (a) each GMS contractor in its area who enters into a contract on or after 1st April 2011; and
- (b) each PMS contractor in its area for which it holds a list of registered patients and who enters into an agreement on or after 1st April 2011,

the opportunity to enter into the arrangements under the Scheme referred to in paragraph (1) for the remainder of the financial year.

(3) A Primary Care Trust is required to enter into any arrangement under the Scheme referred to in paragraph (1) after 31st December 2011, only where—

- (a) two or more GMS or PMS contracts (under at least one of which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) merge and as a result two or more patient lists are combined, resulting in either a new GMS or PMS contract or a varied GMS or PMS contract, and the contractor who is a party to such a new or varied contract wishes to enter into a new arrangement referred to in paragraph (1); or
- (b) a GMS or PMS contract (under which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) splits and as a result the contractor's patient list is divided between two or more GMS or PMS contractors, resulting in either new GMS or PMS contracts or varied GMS or PMS contracts, or a combination of both, and a contractor who is a part to such a new or varied contract wishes to enter into a new arrangement under the Scheme referred to in paragraph (1),

in which case the Primary Care Trust is required to enter into a new arrangement under the Scheme referred to in paragraph (1), and such arrangements must commence on or before the expiry of the period of 28 days beginning with the date of the merger or the split as the case may be.

(4) A Primary Care Trust must—

- (a) consider any proposals put forward by a GMS or PMS contractor which wishes to enter into arrangements under the Scheme referred to in paragraphs (1) and (2) with a view to agreeing them;

- (b) not delay any such consideration unreasonably; and
- (c) not withhold its agreement unreasonably.

(5) A Primary Care Trust is not required to consider and reach a decision in respect of entering into any arrangement under the Scheme referred to in paragraph (1) where a GMS or PMS contractor has failed to provide written proposals in response to the Primary Care Trust's offer to enter into such arrangements within 42 days beginning with the date of the offer.

(6) The arrangement that a Primary Care Trust enters into with a GMS or PMS contractor as part of its Osteoporosis Diagnosis and Prevention Scheme must be in writing and must include—

- (a) a requirement that the contractor—
 - (i) maintain a register of all female registered patients aged 65 and older with fragility fractures sustained on or after 1st April of the financial year in which the contractor enters into the arrangements to participate in the Osteoporosis Diagnosis and Prevention Scheme, or
 - (ii) where the Primary Care Trust had entered into a previous scheme under Direction 9 of the Primary Medical Services (Directed Enhanced Services) (England) Directions 2008(a) or under Direction 8 of these Directions as in force immediately before 1st April 2011, retain any previous register required under those schemes and those registers shall be the register for the purposes of the arrangement referred to in paragraph (1);
- (b) a requirement that the contractor takes reasonable steps to keep such register up to date during the period of the arrangements, including adding and removing patients as appropriate;
- (c) a requirement that the contractor provides the Primary Care Trust with such information as the Primary Care Trust may reasonably require to demonstrate that it has robust systems in place to maintain such a register accurately;
- (d) a requirement that the contractor co-operates with the Primary Care Trust in any reasonable review of such register that relates to its accuracy, including the comparison of reported prevalence and expected prevalence;
- (e) a requirement that the contractor makes relevant entries in the patients' medical records;
- (f) a requirement that before 1st August 2012, the contractor informs the Primary Care Trust (in writing) in respect of the twelve month period ending on 31st March 2012—
 - (i) the proportion of women on the register as at 31st March 2012 who—
 - (aa) are at least aged 65 but not yet aged 75,
 - (bb) have sustained a fragility fracture during the twelve month period ending on 31st March 2012, and
 - (cc) have been referred for a DEXA(b) scan during the twelve month period ending on 31st March 2012;
 - (ii) the proportion of women on the register as at 30th June 2012 who—
 - (aa) as at 31st March 2012 were at least aged 65 but not yet aged 75,
 - (bb) had sustained a fragility fracture during the twelve month period ending on 31st March 2012,

(a) The Primary Medical Services (Directed Enhanced Services) (England) Directions 2008, signed on 1st September 2008 and amended by the Primary Medical Services (Directed Enhanced Services) (England) (Amendment) Directions 2009 signed on 29th January 2009.

(b) A DEXA (dual energy x-ray absorptiometry) scan is a test that measures the density of bones and is used for the diagnosis of osteoporosis and to assess the risk of fracture.

- (cc) have had a diagnosis of osteoporosis confirmed by DEXA scan during the previous fifteen month period ending on 30th June 2012, and
- (dd) are receiving treatment with a bone-sparing agent; and
- (iii) the proportion of women on the register as at 31st March 2012 who—
 - (aa) are at least aged 75,
 - (bb) have sustained a fragility fracture in the previous twelve months, and
 - (cc) are receiving treatment with a bone-sparing agent;
- (g) details of the arrangements for the provision of information by the Primary Care Trust and by the contractor, in addition to any information the contractor is required to provide in accordance with sub-paragraphs (c), (d) and (f);
- (h) details of the arrangements for the monitoring of the arrangements by the Primary Care Trust;
- (i) in the case of PMS contractors, the amount of the payments to be made to the contractor for meeting its obligations under the arrangements and in determining the appropriate level of those payments the Primary Care Trust must have regard to the amounts of payments under section 7LB of the Statement of Financial Entitlements,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the arrangements comprise part of the contractor's contract and the requirements of the arrangements are conditions of the contract.”.

Insertion of new direction 12A

10. After direction 12 insert—

“Patient Participation Scheme

12A.—(1) As part of its Patient Participation Scheme, each Primary Care Trust must before 31st May 2011 and subject to paragraph (3) offer to—

- (a) each GMS contractor in its area who has entered into a contract which subsists on 1st April 2011; and
- (b) each PMS contractor in its area for which it holds a list of registered patients and who has entered into an agreement which subsists on 1st April 2011,

the opportunity to enter into arrangements under the Scheme in respect of a period ending on 31st March 2013.

(2) A Primary Care Trust must subject to paragraph (3) offer to—

- (a) each GMS contractor in its area who enters into a contract on or after 1st April 2011; and
- (b) each PMS contractor in its area for which it holds a list of registered patients and who enters into an agreement on or after 1st April 2011,

the opportunity to enter into the arrangements under the Scheme referred to in paragraph (1) for the remainder of the period ending on 31st March 2013.

(3) A Primary Care Trust is required to enter into any arrangement under the Scheme referred to in paragraph (1)—

- (a) after 31st December 2011, in respect of any part of the twelve month period ending 31st March 2012; and
- (b) after 31st December 2012, in respect any part of the twelve month period ending on 31st March 2013,

only where paragraph (4) applies.

(4) This paragraph applies where—

- (a) two or more GMS or PMS contracts (under at least one of which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) merge and as a result two or more patient lists are combined, resulting in either a new GMS or PMS contract or a varied GMS or PMS contract, and the contractor who is a party to such a new or varied contract wishes to enter into a new arrangement referred to in paragraph (1); or
- (b) a GMS or PMS contract (under which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) splits and as a result the contractor's patient list is divided between two or more GMS or PMS contractors, resulting in either new GMS or PMS contracts or varied GMS or PMS contracts, or a combination of both, and a contractor who is a party to such a new or varied contract wishes to enter into a new arrangement under the Scheme referred to in paragraph (1),

in which case the Primary Care Trust is required to enter into a new arrangement under the Scheme referred to in paragraph (1), and such arrangements must commence on or before the expiry of the period of 28 days beginning with the date of the merger or the split as the case may be.

(5) A Primary Care Trust must—

- (a) consider any proposals put forward by a GMS or PMS contractor which wishes to enter into arrangements under the Scheme under paragraphs (1) and (2) with a view to agreeing them;
- (b) not delay any such consideration unreasonably; and
- (c) not withhold its agreement unreasonably.

(6) A Primary Care Trust is not required to consider and reach a decision in respect of entering into any arrangement under the Scheme referred to in paragraphs (1) and (2) where a GMS or PMS contractor has failed to provide written proposals in response to the Primary Care Trust's offer to enter into such arrangements within 42 days beginning with the date of the offer.

(7) The arrangement that a Primary Care Trust enters into with a GMS or PMS contractor as part of its Patient Participation Scheme must be in writing and must include—

- (a) a requirement that the contractor establish a Patient Reference Group comprising only of registered patients;
- (b) a requirement that the contractor uses its best endeavours to ensure its Patient Reference Group is representative of its registered patients;
- (c) a requirement that the contractor, if it has not already done so, establishes a website to include information on the services provided by the contractor under the terms of its primary medical services contract—
 - (i) no later than 29th February 2012, where the contractor enters into the arrangements referred to in paragraph (1) to provide services during any part of the eleven month period ending on that date; or
 - (ii) no later than 28th February 2013, where the contractor first enters into the arrangements referred to in paragraph (1) on or after 1st March 2012 but before 28th February 2013;
- (d) a requirement that the contractor develops, in consultation with the Patient Reference Group, a local practice survey to obtain the views of a cross-section of the contractor's registered patients;
- (e) a requirement that the contractor agrees with the Patient Reference Group the issues which are a priority and which are to be included in a local practice survey and may include issues relating—

- (i) to the accessibility to the primary medical services provided, including opening times, ability to make appointments in advance, waiting times at the practice and the effectiveness of telephone services;
- (ii) to the experience relating to services registered patients received from health professionals providing primary medical services and contact with other persons employed by the contractor;
- (iii) to the premises from which the contractor provides primary medical services; and
 - (iv) to such other matters as may be agreed in order to assist the contractor to consider how the delivery of primary medical services may be improved;
- (f) a requirement that the contractor carries out and collates the finding of a local practice survey—
 - (i) at least once in the period commencing on the date the contractor enters into the arrangements and ending on 31st March 2012; and
 - (ii) where the contractor has entered into arrangements in respect of the twelve month ending 31st March 2013, at least once in that period;
- (g) a requirement that the contractor—
 - (i) informs the Patient Reference Group of the findings of the local practice survey;
 - (ii) provides an opportunity for the Patient Reference Group to comment and discusses the findings; and
 - (iii) agree with the Patient Reference Group an action plan setting out priorities of findings and any proposals arising out of those findings;
- (h) a requirement that if, as a consequence of the findings or proposals arising out of the local practice survey, the contractor wishes to implement changes in the manner in which it delivers primary medical services, the contractor must—
 - (i) seek the agreement of the Patient Reference Group to implement such changes; and
 - (ii) where such changes are significant and the Patient Reference Group does not agree to such changes or the changes relate to, or impact on, the terms of the primary medical services contract, discuss the proposed changes with the Primary Care Trust and obtain agreement of the Primary Care Trust before such changes are implemented;
- (i) a requirement that the contractor provides a copy of a report to the Primary Care Trust (to be known as “the Local Patient Participation Report”) setting out the information specified in sub-paragraph (j);
- (j) a requirement that the contractor publishes a Local Patient Participation Report (“LPP Report”) on the contractor’s website—
 - (i) where the contractor entered into the arrangements under the Scheme during any part of the twelve month period ending on 31st March 2012, a first LPP Report no later than 31st March 2012, and a second LPP Report no later than 31st March 2013; and
 - (ii) where the contractor first entered into the arrangements under the Scheme after 31st March 2012, a LPP Report, no later than 31st March 2013;
- (k) a requirement that the contractor includes in the LPP Report—
 - (i) a description of the profile of the members of the Patient Reference Group;
 - (ii) the steps taken by the contractor to ensure that the Patient Reference Group is representative of its registered patients and where a category of patients is not represented, the steps the contractor took in an attempt to engage that category;

- (iii) details of the steps taken to determine and reach agreement on the issues which had priority and were included in the local practice survey;
- (iv) the manner in which the contractor sought to obtain the views of its registered patients;
- (vi) details of the steps taken by the contractor to provide an opportunity for the Patient Reference Group to discuss the contents of the action plan;
- (v) details of the action plan setting out how the finding or proposals arising out of the local practice survey can be implemented and, if appropriate, reasons why any such findings or proposals should not be implemented;
- (vi) a summary of the evidence including any statistical evidence relating to the findings or basis of proposals arising out of the local practice survey;
- (vii) details of the action which the contractor—
 - (aa) and, if relevant, the Primary Care Trust, intend to take as a consequence of discussions with the Patient Reference Group in respect of the results, findings and proposals arising out of the local practice survey; and
 - (bb) where it has participated in the Scheme for the year, or any part thereof, ending 31st March 2012, has taken on issues and priorities as set out in the Local Patient Participation Report;
- (viii) the opening hours of the practice premises and the method of obtaining access to services throughout the core hours; and
- (ix) where the contractor has entered into arrangements under an extended hours access scheme, the times at which individual health care professionals are accessible to registered patients;
- (l) a requirement that the contractor consider whether any amendments are necessary to any of its published information relating to the services provided by the contractor as a consequences of the implementation of any changes following a finding or proposal arising out of the Local Practice Survey;
- (m) details of the arrangements for the monitoring of the arrangements by the Primary Care Trust; and
- (n) in the case of PMS contractors, the amount of the payments to be made to the contractor for meeting its obligations under the arrangements and in determining the appropriate level of those payments the Primary Care Trust must have regard to the amounts of payments under section 7M of the Statement of Financial Entitlements,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the arrangements comprise part of the contractor's contract and the requirements of the arrangements are conditions of the contract.”.

Signed by authority of the Secretary of State for Health



A member of the Senior Civil Service
Department of Health

Date: 31st March 2011