STATUTORY INSTRUMENTS

2012 No. 970

The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2012

PART 2

AMENDMENT OF THE GMS CONTRACTS REGULATIONS

Amendment of regulation 2

- 2. In regulation 2(1) (interpretation) of the GMS Contracts Regulations—
 - (a) immediately after the definition of "the 2010 Order"(1), insert ""the 2006 Act" means the National Health Service Act 2006(2)";
 - (b) in the definition of "additional services", in each of sub-paragraphs (c) and (d), for "vaccinations" substitute "vaccines";
 - (c) in the definition of "assessment panel", for "paragraphs 31 and 35", substitute "paragraph 35";
 - (d) in the definition of "childhood vaccinations and immunisations", for "vaccination", substitute "vaccines"; and
 - (e) immediately after the definition of "patient", insert ""Patient Choice Scheme" means the scheme of that name established by the Secretary of State under which primary medical services may be provided to persons under arrangements made in accordance with directions given by the Secretary of State under section 8 of the 2006 Act(3);".

Amendment of regulation 18

- **3.**—(1) Regulation 18 (services generally) of the GMS Contracts Regulations is amended as follows.
 - (2) After paragraph (1), insert—
 - "(1A) A contract—
 - (a) may also specify an area, other than the area referred to in paragraph (1)(d), which is to be known as the outer boundary area as respects which a patient—
 - (i) who moves into that outer boundary area to reside; and
 - (ii) who wishes to remain on the contractor's list of patients,

may remain on that list if the contractor so agrees, notwithstanding that the patient no longer resides in the area referred to in paragraph (1)(d); and

⁽¹⁾ Regulation 2(a) of the National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2010 (S.I. 2010/578) inserts the definition "2010 Order" into the GMS Contracts Regulations.

^{(2) 2006} c.41.

⁽³⁾ See the Primary Medical Services (Patient Choice Scheme) Directions 2012 signed on 28th March 2012 and published on the Department of Health website www.dh.gov.uk.

- (b) which specifies an outer boundary must specify that where a patient remains on the contractor's list of patients as a consequence of sub-paragraph (a) the outer boundary area is to be treated as part of the practice area for the purposes of the application of any other terms and conditions of the contract in respect of that patient."
- (3) Omit paragraph (4).

Insertion of new regulation 26A

4.—(1) After regulation 26 (other contractual terms) of the GMS Contracts Regulations, insert—

"Variation of contractual terms in respect of entering into arrangements under the Patient Choice Scheme

- **26A.**—(1) This regulation applies where the contractor and the Primary Care Trust enter into arrangements under the Patient Choice Scheme.
 - (2) The terms of the contract—
 - (a) which have the same effect as the provisions specified in paragraph (3) must be varied in accordance with paragraph (4); and
 - (b) must be varied to include terms which have the same effect as the provisions specified in paragraphs (5) to (7),

but only to the extent that such variations relate to the provision of primary medical services to patients who wish to receive such services under arrangements made in accordance with the Patient Choice Scheme with effect from the start of the day on which such arrangements commence and for the period ending at the end of the day which is the date of the termination of those arrangements, which must be no later than 31st March 2013.

- (3) The terms of the contract specified in this paragraph are—
 - (a) regulation 15 (essential services);
 - (b) regulation 20 (arrangements to access services throughout core hours);
 - (c) the provisions which provide for the contractor to provide out of hours services; and
 - (d) in Schedule 6 (other contractual terms)—
 - (i) paragraph 2(1) (attendance at practice premises);
 - (ii) paragraph 3(2)(a) (attendance outside practice premises); and
 - (iii) paragraph 17(2) (refusal of applications for inclusion in the list of patients).
- (4) The contract must include terms which have the effect of temporarily releasing the contractor and the Primary Care Trust from all obligations, payments, rights and liabilities relating to those terms (and only those terms) which have the same effect as the provisions specified in paragraph (3)—
 - (a) including any right to enforce those terms only in respect of the provision of primary medical services to patients who wish to receive such services under arrangements made in accordance with the Patient Choice Scheme; and
 - (b) only where, in the opinion of the contractor, it is not clinically appropriate or practical to provide the services or access to such services in accordance with those terms or to comply with those terms, under arrangements made under the Patient Choice Scheme.
- (5) The contract must also include a term which has the effect of requiring the contractor to notify a person in writing that where the contractor is minded to accept that person onto

its list of patients in accordance with the Patient Choice Scheme the contractor is under no obligation to provide—

- (a) essential services, in a case where at the time treatment is required, it is not clinically appropriate or practical to provide primary medical services given the particular circumstances of the patient;
- (b) out of hours services, in a case where at the time treatment is required, it is not clinically appropriate or practical to provide such services given the particular circumstances of the patient; or
- (c) additional services (within the meaning of regulation 2) to the patient if it is not clinically appropriate or practical to provide such services given the particular circumstances of the patient.
- (6) The contract must also include terms to have the effect of providing that immediately after the date of the termination of the arrangements under the Patient Choice Scheme, the variations made as a consequence of paragraph (2) must terminate save to the extent necessary in respect of enforcing any obligation, condition, payment, right and liability arising from those terms prior to the date of termination.
- (7) In a case where primary medical services are provided to a patient under arrangements made in accordance with the Patient Choice Scheme but that patient is not on the contractor's list of patients, the contract must contain a term which has the effect of requiring payment to be made under the contract and such payment must be made in accordance with the provisions in regulation 22(2) and (3) (finance) and the GMS Statement of Financial Entitlements.".

Amendment of Schedule 2

- **5.**—(1) Schedule 2 (Additional Services) to the GMS Contracts Regulations is amended as follows.
 - (2) For paragraph 4, substitute—

"Vaccines and Immunisations

- **4.**—(1) This paragraph applies to a contractor whose contract includes the provision of vaccines and immunisations but does not apply in the case of the provision of—
 - (a) childhood immunisations; and
 - (b) the combined Haemophilus influenza type B and Meningitis C booster vaccine.
 - (2) A contractor must comply with the requirements in sub-paragraph (3) and (4).
 - (3) The contractor must—
 - (a) offer to provide to patients, all vaccines and immunisations (other than those mentioned in sub-paragraph (1)(a) and (b)) of the type and in the circumstances which are set out in the GMS Statement of Financial Entitlements;
 - (b) taking into account the individual circumstances of the patient, consider whether immunisation ought to be administered by the contractor or other health professional or a prescription form ought to be provided for the purpose of the patient selfadministering immunisation;
 - (c) provide appropriate information and advice to patients about such vaccines and immunisation;
 - (d) record in the patient's record, any refusal of the offer referred to in paragraph (a);
 - (e) where the offer is accepted and immunisation is to be administered by the contractor or other health professional, include in the patient's record—

- (i) the patient's consent to immunisation or the name of the person who gave consent to immunisation and that person's relationship to the patient;
- (ii) the batch numbers, expiry date and title of the vaccine;
- (iii) the date of administration;
- (iv) in the case where two vaccines are administrated by injection, in close succession, the route of the administration and the injection site of each vaccine;
- (v) any contraindications to the vaccine; and
- (vi) any adverse reaction to the vaccine; and
- (f) where the offer is accepted and the immunisation is not to be administered by the contractor or other health professional, issue a prescription form for the purpose of self-administration by the patient.
- (4) The contractor must ensure that all staff involved in the administration of immunisations are trained in the recognition and initial treatment of anaphylaxis.
- (5) In this paragraph "patient's record" means the record which is kept in accordance with paragraph 73 of Schedule 6.".
- (3) In paragraph 5—
 - (a) in the heading for that paragraph and in sub-paragraph (1), for "childhood vaccinations and immunisations", substitute "childhood vaccines and immunisations";
 - (b) for sub-paragraph (2)(a), substitute—
 - "offer to provide to children, all vaccines and immunisations of the type and in the circumstances which are set out in the GMS Statement of Financial Entitlements;";
 - (c) in sub-paragraph (2)(b), for "vaccinations" substitute "vaccines"; and
 - (d) in sub-paragraph (2)(d)—
 - (i) omit "vaccinations and";
 - (ii) in sub-paragraph (i), omit "vaccination or"; and
 - (iii) in sub-paragraphs (v) and (vi), in each place "vaccination or immunisation" occurs, substitute "vaccine".

Amendment of Schedule 6

- **6.**—(1) Schedule 6 (other contractual terms) to the GMS Contracts Regulations is amended as follows.
- (2) For paragraph 17(2) (refusal of applications for inclusion in the list of patients or for acceptance as a temporary resident), substitute—
 - "(2) The reasonable grounds referred to in paragraph (1) may, in the case of an application made under paragraph 15, include the ground that the applicant—
 - (a) does not live in the contractor's practice area; or
 - (b) lives in the outer boundary area (the area referred to in regulation 18(1A)).".
- (3) Omit paragraph 29 (closure of lists of patients) and insert after paragraph 28 (termination of responsibility for patients not registered with the contractor)—

"Application for closure of list of patients

- **29A.**—(1) A contractor which wishes to close its list of patients must send a written application ("the Application") to close its list to the Primary Care Trust and the Application must include the following details—
 - (a) the options which the contractor has considered, rejected or implemented in an attempt to relieve the difficulties which the contractor has encountered in respect of its open list and, if any of the options were implemented, the level of success in reducing or extinguishing such difficulties;
 - (b) any discussions between the contractor and its patients and a summary of those discussions including whether in the opinion of those patients the list of patients should or should not be closed;
 - (c) any discussions between the contractor and other contractors in the practice area and a summary of the opinion of the other contractors as to whether the list of patients should or should not be closed;
 - (d) the period of time during which the contractor wishes its list of patients to be closed and that period must not be less than 3 months and not more than 12 months;
 - (e) any reasonable support from the Primary Care Trust which the contractor considers would enable its list of patients to remain open or would enable the period of proposed closure to be minimised;
 - (f) any plans the contractor may have to alleviate the difficulties mentioned in that Application during the period the list of patients may be closed in order for that list to reopen at the end of the proposed closure period without the existence of those difficulties; and
 - (g) any other information which the contractor considers ought to be drawn to the attention of the Primary Care Trust.
- (2) The Primary Care Trust must acknowledge receipt of the Application within a period of 7 days starting on the date the Application was received by the Primary Care Trust.
- (3) The Primary Care Trust must consider the Application and may request such other information from the contractor which it requires to enable it to consider the Application.
 - (4) The Primary Care Trust must enter into discussions with the contractor concerning—
 - (a) the support which the Primary Care Trust may give the contractor; or
 - (b) changes which the Primary Care Trust or contractor may make,

to enable the contractor to keep its list of patients open.

- (5) The Primary Care Trust and contractor must, throughout the discussions referred to in sub-paragraph (4), use its reasonable endeavours to achieve the aim of keeping the contractor's list of patients open.
- (6) The Primary Care Trust or the contractor may, at any stage during the discussions, invite the Local Medical Committee for its area (if any) to attend any meetings arranged between the Primary Care Trust and contractor to discuss the Application.
- (7) The Primary Care Trust may consult such persons as it appears to the Primary Care Trust may be affected by the closure of the contractor's list of patients, and if it does so, the Primary Care Trust must provide to the contractor a summary of the views expressed by those consulted in respect of the Application.
- (8) The Primary Care Trust must enable the contractor to consider and comment on all the information before the Primary Care Trust makes a decision in respect of the Application.

- (9) A contractor may withdraw its Application at any time before the Primary Care Trust makes a decision in respect of that Application.
- (10) Within a period of 21 days starting on the date of receipt of the Application (or within such longer period as the parties may agree), the Primary Care Trust must make a decision—
 - (a) to approve the Application and determine the date the closure is to take effect and the date the list of patients is to reopen; or
 - (b) to reject the Application.
- (11) The Primary Care Trust must notify the contractor of its decision to approve the Application in accordance with paragraph 29B, or in the case where the Application is rejected, in accordance with paragraph 29C.
- (12) A contractor must not submit more than one application to close its list of patients in any period of 12 months starting on the date on which the Primary Care Trust makes its decision on the Application unless—
 - (a) paragraph 29C applies; or
 - (b) there has been a change in the circumstances of the contractor which affects its ability to deliver services under the contract.

Approval of an application to close a list of patients

- **29B.**—(1) Where the Primary Care Trust approves an application to close a list of patients, it must—
 - (a) notify the contractor of its decision in writing as soon as possible and the notification ("the closure notice") must include the details referred to in sub-paragraph (2); and
 - (b) at the same time as it notifies the contractor, send a copy of the closure notice to the Local Medical Committee for its area (if any) and to any person it consulted in accordance with paragraph 29A(7).
 - (2) The closure notice must include—
 - (a) the period of time for which the contractor's list of patients will be closed which must be—
 - (i) the period specified in the application to close the list of patients; or
 - (ii) in the case where the Primary Care Trust and contractor have agreed in writing a different period, that different period,

and in either case, the period must be not less than 3 months and not more than 12 months;

- (b) the date from which the closure of the list of patients is to take effect; and
- (c) the date from which the list of patients is to re-open.
- (3) Subject to paragraph 29E, a contractor must close its list of patients with effect from the date the closure of the list of patients is to take effect and the list of patients must remain closed for the duration of the closure period as specified in the closure notice.

Rejection of an application to close a list of patients

- **29C.**—(1) Where a Primary Care Trust rejects an application to close a list of patients it must—
 - (a) notify the contractor of its decision in writing as soon as possible and the notification must include the reasons for the rejection of the application; and

- (b) at the same time as it notifies the contractor, send a copy of the notification to the Local Medical Committee for its area (if any) and to any person it consulted in accordance with paragraph 29A(7).
- (2) Subject to sub-paragraph (3), if a Primary Care Trust makes a decision to reject a contractor's application to close its list of patients, the contractor must not make a further application until—
 - (a) the end of the period of 3 months, starting on the date of the decision of the Primary Care Trust to reject; or
 - (b) the end of the period of 3 months, starting on the date of the final determination in respect of a dispute arising from the decision to reject the application made pursuant to the NHS dispute resolution procedure (or any court proceedings),

whichever is the later.

(3) A contractor may make a further application to close its list of patients where there has been a change in the circumstances of the contractor which affects its ability to deliver services under the contract.

Application for an extension of a closure period

- **29D.**—(1) A contractor may apply to extend a closure period by sending a written application to extend the closure period no later than 8 weeks before the date that period is due to expire.
 - (2) The application to extend the closure period must include—
 - (a) details of the options the contractor has considered, rejected or implemented in an attempt to relieve the difficulties which have been encountered during the closure period or which may be encountered when the closure period expires;
 - (b) the period of time during which the contractor wishes its list of patients to remain closed, which extended period of desired closure must not be more than 12 months;
 - (c) details of any reasonable support from the Primary Care Trust which the contractor considers would enable its list of patients to re-open or would enable the proposed extension of the closure period to be minimised;
 - (d) details of any plans the contractor may have to alleviate the difficulties mentioned in the application to extend the closure period in order for the list of patients to reopen at the end of the proposed extension of the closure period without the existence of those difficulties; and
 - (e) any other information which the contractor considers ought to be drawn to the attention of the Primary Care Trust.
- (3) The Primary Care Trust must acknowledge receipt of the application for an extension to the closure period within a period of 7 days starting on the date the application was received by the Primary Care Trust.
- (4) The Primary Care Trust must consider the application for an extension to the closure period and may request such other information from the contractor which it requires to enable it to consider that application.
 - (5) The Primary Care Trust may enter into discussions with the contractor concerning—
 - (a) the support which the Primary Care Trust may give the contractor; or
 - (b) changes which the Primary Care Trust or contractor may make,

to enable the contractor to re-open its list of patients.

- (6) Within a period of 14 days starting on the date of receipt of the application to extend the closure period (or within such longer period as the parties may agree), the Primary Care Trust must make a decision.
- (7) The Primary Care Trust must notify the contractor of its decision to approve or reject the application to extend the closure period as soon as possible after making its decision.
- (8) Where the Primary Care Trust approves the application to extend the closure period, it must—
 - (a) notify the contractor of its decision in writing and the notification ("the extended closure notice") shall include the details referred to in sub-paragraph (9); and
 - (b) at the same time as it notifies the contractor, send a copy of the extended closure notice to the Local Medical Committee for its area (if any) and to any person it consulted in accordance with paragraph 29A(7).
 - (9) The extended closure notice must include—
 - (a) the period of time for which the contractor's list of patients will remain closed which must be—
 - (i) the period specified in the application to extend the closure period; or
 - (ii) in the case where the Primary Care Trust and contractor have agreed in writing a different period to the period specified in the application to extend the closure period, the period which is agreed,

and in either case, the period ("the extended closure period"), must be not less than 3 months and not more than 12 months;

- (b) the date from which the extended closure period is to take effect; and
- (c) the date on which the list of patients is to re-open.
- (10) Where a Primary Care Trust rejects an application to extend the closure period it must—
 - (a) notify the contractor of its decision in writing and the notification must include the reasons for the rejection of the application; and
 - (b) at the same time as it notifies the contractor, send a copy of the notification to the Local Medical Committee for its area (if any).
- (11) Where an application for an extension of the closure period is made in accordance with sub-paragraphs (1) and (2), the list of patients will remain closed pending—
 - (a) the determination by the Primary Care Trust of the application for an extension of the closure period; or
 - (b) the contractor ceasing to pursue any dispute arising from the application for an extension of the closure period pursuant to the NHS dispute resolution procedure (or any court proceedings),

whichever is the later.

Re-opening of list of patients

- **29E.** The contractor may re-open its list of patients before the expiry of the closure period if the Primary Care Trust and contractor agree that the contractor should re-open its list of patients.".
- (4) Omit paragraph 30 (approval of closure notice by the Primary Care Trust) and paragraph 31 (rejection of closure notice by the Primary Care Trust).

- (5) Paragraph 35 (assignment to closed lists: determinations of the assessment panel) is amended as follows—
 - (a) in sub-paragraph (3), for "paragraph 31(5)", substitute "sub-paragraph (3A)".
 - (b) after sub-paragraph (3), insert—
 - "(3A) The members of the assessment panel must be—
 - (a) the Chief Executive of the Primary Care Trust of which the assessment panel is a committee or sub-committee;
 - (b) a person representative of patients in an area other than that of the Primary Care Trust which is a party to the contract;
 - (c) a person representative of a Local Medical Committee which does not represent practitioners in the area of the Primary Care Trust which is a party to the contract."
 - (6) In paragraph 73(4) (patient records), for sub-paragraph (c), substitute—
 - "(c) the contractor is aware of, and has signed an undertaking that it will have regard to the guidelines contained in "The Good Practice Guidelines for GP electronic patient records (Version 4) published on 21st March 2011(4).".
 - (7) After paragraph 76 (Practice Leaflet), insert—

"Provision of information on website

76A. In the case where a contractor has a website, the contractor must publish on that website details of the practice area, including the area known as the outer boundary area (within the meaning given in regulation 18(1A)), by reference to a sketch diagram, plan or postcode."

Omission of Schedule 8

7. Omit Schedule 8 (Closure Notice) to the GMS Contracts Regulations.

Amendment of Schedule 10

- **8.** In Schedule 10 (information to be included in practice leaflets) to the GMS Contracts Regulations, for paragraph 7, substitute—
 - "7. The contractor's practice area, including the area known as the outer boundary area (within the meaning given in regulation 18(1A)), by reference to a sketch diagram, plan or postcode."