

SCHEDULE 1

Regulation 16

ADDITIONAL SERVICES

Additional services generally

1. The contractor shall provide, in relation to each additional service, such facilities and equipment as are necessary to enable it properly to perform that service.

Cervical screening

2.—(1) A contractor whose contract includes the provision of cervical screening services shall—

- (a) provide all the services described in sub-paragraph (2); and
- (b) make such records as are referred to in sub-paragraph (3).

(2) The services referred to in sub-paragraph (1)(a) are—

- (a) the provision of any necessary information and advice to assist women identified by the Health Board as recommended nationally for a cervical screening test in making an informed decision as to participation in the NHS Scotland Cervical Screening Programme;
- (b) the performance of cervical screening tests on women who have agreed to participate in that Programme;
- (c) arranging for women to be informed of the results of the test; and
- (d) ensuring that test results are followed up appropriately.

(3) The records referred to in sub-paragraph (1)(b) are an accurate record of the carrying out of a cervical screening test, the result of the test and any clinical follow up requirements.

Contraceptive services

3.—(1) A contractor whose contract includes the provision of contraceptive services shall make available to all its patients who request such services the services described in sub-paragraph (2).

(2) The services referred to in sub-paragraph (1) are—

- (a) the giving of advice about the full range of contraceptive methods;
- (b) where appropriate, the medical examination of patients seeking such advice;
- (c) the treatment of such patients for contraceptive purposes and the prescription of contraceptive substances and appliances (excluding the fitting and implanting of intrauterine devices and implants);
- (d) the giving of advice about emergency contraception and where appropriate, the supplying or prescribing of emergency hormonal contraception or, where the contractor has a conscientious objection to emergency contraception, prompt referral to another provider of primary medical services who does not have such conscientious objections;
- (e) the provision of advice and referral in cases of unplanned or unwanted pregnancy, including advice about the availability of free pregnancy testing in the practice area and, where appropriate, where the contractor has a conscientious objection to the termination of pregnancy, prompt referral to another provider of primary medical services who does not have such conscientious objections;
- (f) the giving of initial advice about sexual health promotion and sexually transmitted infections; and
- (g) the referral as necessary for specialist sexual health services, including tests for sexually transmitted infections.

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Vaccinations and immunisations

4.—(1) A contractor whose contract includes the provision of vaccinations and immunisations shall comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor shall—

- (a) offer to provide to patients all vaccinations and immunisations (excluding childhood vaccinations and immunisations) of a type and in the circumstances for which a fee was provided for under the 2003–04 Statement of Fees and Allowances made under regulation 35 of the National Health Service (General Medical Services) (Scotland) Regulations 1995⁽¹⁾ other than influenza vaccination;
- (b) provide appropriate information and advice to patients about such vaccinations and immunisations;
- (c) record in the patient’s record kept in accordance with paragraph 66 of Schedule 5 any refusal of the offer referred to in paragraph (a);
- (d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient’s record kept in accordance with paragraph 66 of Schedule 5—
 - (i) the patient’s consent to the vaccination or immunisation or the name of the person who gave consent to the vaccination or immunisation and the person’s relationship to the patient,
 - (ii) the batch numbers, expiry date and title of the vaccine,
 - (iii) the date of administration,
 - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine,
 - (v) any contraindications to the vaccination or immunisation, and
 - (vi) any adverse reactions to the vaccination or immunisation.

(3) The contractor shall ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

Childhood vaccination and immunisation

5.—(1) A contractor whose contract includes the provision of childhood vaccinations and immunisations shall comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor shall—

- (a) offer to provide to children all vaccinations and immunisations of a type and in the circumstances for which a fee was provided for under the 2003-04 Statement of Fees and Allowances made under regulation 35 of the National Health Service (General Medical Services) (Scotland) Regulations 1995;
- (b) provide appropriate information and advice to patients and, where appropriate, their parents, about such vaccinations and immunisations;
- (c) record in the patient’s record kept in accordance with paragraph 66 of Schedule 5 any refusal of the offer referred to in paragraph (a);
- (d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient’s record kept in accordance with paragraph 66 of Schedule 5—
 - (i) the name of the person who gave consent to the vaccination or immunisation and the person’s relationship to the patient;

(1) S.I.1995/416. Regulation 35 was amended by S.I. 1998/1600, 1999/749 and S.S.I. 1995/54 and 2000/111.

- (ii) the batch numbers, expiry date and title of the vaccine;
- (iii) the date of administration;
- (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
- (v) any contraindications to the vaccination or immunisation; and
- (vi) any adverse reactions to the vaccination or immunisation.

(3) The contractor shall ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

Child health surveillance

6.—(1) A contractor whose contract includes the provision of child health surveillance services shall, in respect of any child under the age of five for whom it has responsibility under the contract—

- (a) provide all the services described in sub-paragraph (2), other than any examination so described which the parent refuses to allow the child to undergo, until the date upon which the child attains the age of 5 years; and
- (b) maintain such records as are specified in sub-paragraph (3).

(2) The services referred to in sub-paragraph (1)(a) are—

- (a) the monitoring—
 - (i) by the consideration of any information concerning the child received by or on behalf of the contractor; and
 - (ii) on any occasion when the child is examined or observed by or on behalf of the contractor (whether pursuant to (b) below, or otherwise),

of the health, well-being and physical, mental and social development (all of which characteristics are referred to in this paragraph as “development”) of the child while under the age of 5 years with a view to detecting any deviations from normal development;

- (b) the examination of the child at a frequency that has been agreed with the Health Board in accordance with the nationally agreed evidence based programme set out in the fourth edition of “Health for all Children”(2).

(3) The records mentioned in sub-paragraph (1)(b) are an accurate record of—

- (a) the development of the child while under the age of 5 years, compiled as soon as is reasonably practicable following the first examination of that child and, where appropriate, amended following each subsequent examination mentioned in that sub-paragraph; and
- (b) the responses (if any) to offers made to the child’s parent for the child to undergo any examination referred to in sub-paragraph (2)(b).

Maternity medical services

7.—(1) A contractor whose contract includes the provision of maternity medical services shall provide—

- (a) to female patients who have been diagnosed as pregnant all necessary maternity medical services throughout the ante-natal period;
- (b) to female patients and their babies all necessary maternity medical services throughout the post-natal period other than neonatal checks;

(2) David Hall and David Elliman, January 2003, Oxford University Press, ISBN 0-19-85188-X.

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- (c) all necessary maternity medical services to female patients whose pregnancy has terminated as a result of miscarriage or abortion or, where the contractor has a conscientious objection to the termination of pregnancy, prompt referral to another provider of primary medical services who does not have such conscientious objections.
- (2) In this paragraph—
- “ante-natal period” means the period from the start of the pregnancy to the onset of labour;
 - “maternity medical services” means—
 - (a) in relation to female patients (other than babies) all primary medical services relating to pregnancy, excluding intra partum care; and
 - (b) in relation to babies, any primary medical services necessary in their first 14 days of life;
 - “post-natal period” means the period starting from the conclusion of delivery of the baby or the patient’s discharge from secondary care services, whichever is the later, and ending on the fourteenth day after the birth.

Minor surgery

- 8.—**(1) A contractor whose contract includes the provision of minor surgery shall comply with the requirements in sub-paragraphs (2) and (3).
- (2) The contractor shall make available to patients where appropriate—
- (a) curettage;
 - (b) cautery; and
 - (c) cryocautery of warts, verrucae and other skin lesions.
- (3) The contractor shall ensure that its record of any treatment provided under this paragraph includes the consent of the patient to that treatment.

SCHEDULE 2

Regulation 17

OPT OUTS OF ADDITIONAL AND OUT OF HOURS SERVICES

Opt outs of additional services: general

- 1.—**(1) In this Schedule—
- “opt out notice” means a notice given under sub-paragraph (5) to opt out permanently or temporarily of the provision of the additional service;
 - “permanent opt out” in relation to the provision of an additional service that is funded through the global sum, means the termination of the obligation under the contract for the contractor to provide that service; and “opt out permanently” shall be construed accordingly;
 - “permanent opt out notice” means an opt out notice to opt out permanently;
 - “preliminary opt out notice” means a notice given under sub-paragraph (2) that a contractor wishes to opt out permanently or temporarily of the provision of an additional service;
 - “temporary opt out” in relation to the provision of an additional service that is funded through the global sum, means the suspension of the obligation under the contract for the contractor to provide that service for a period of more than six months and less than twelve months and includes an extension of a temporary opt out and “opt out temporarily” and “opted out temporarily” shall be construed accordingly; and

“temporary opt out notice” means an opt out notice to opt out temporarily.

(2) A contractor who wishes to opt out permanently or temporarily shall give to the Health Board in writing a preliminary opt out notice which shall state the reasons for wishing to opt out.

(3) As soon as is reasonably practicable and in any event within the period of 7 days beginning with the receipt of the preliminary opt out notice by the Health Board, the Health Board shall enter into discussions with the contractor concerning the support which the Health Board may give the contractor, or concerning other changes which the Health Board or the contractor may make, which would enable the contractor to continue to provide the additional service and the Health Board and the contractor shall use reasonable endeavours to achieve this aim.

(4) The discussions mentioned in sub-paragraph (3) shall be completed within the period of 10 days beginning with the date of the receipt of the preliminary opt out notice by the Health Board or as soon as reasonably practicable thereafter.

(5) Subject to sub-paragraph (9), if following the discussions mentioned in sub-paragraph (3), the contractor still wishes to opt out of the provision of the additional service, it shall send an opt out notice to the Health Board.

(6) An opt out notice shall specify—

(a) the additional service concerned;

(b) whether the contractor wishes to—

(i) opt out permanently; or

(ii) opt out temporarily;

(c) the reasons for wishing to opt out;

(d) the date from which the contractor would like the opt out to commence, which must—

(i) in the case of a temporary opt out be at least 14 days after the date of service of the opt out notice, and

(ii) in the case of a permanent opt out must be the day either three or six months after the date of service of the opt out notice; and

(e) in the case of a temporary opt out, the desired duration of the opt out.

(7) Where a contractor has given two previous temporary opt out notices within the period of 3 years ending with the date of the service of the latest opt out notice (whether or not the same additional service is concerned), the latest opt out notice shall be treated as a permanent opt out notice (even if the opt out notice says that the contractor wishes to opt out temporarily).

(8) Paragraph 2 applies following the giving of a temporary opt out notice and paragraph 3 applies following the giving of a permanent opt out notice or a temporary opt out notice which pursuant to sub-paragraph (7) is treated as a permanent opt out notice.

(9) No temporary opt out notice may be served by a contractor prior to 1st April 2004.

Temporary opt outs and permanent opt outs following temporary opt outs

2.—(1) As soon as is reasonably practicable and in any event within the period of 7 days beginning with the date of receipt of a temporary opt out notice under paragraph 1(5), the Health Board shall—

(a) approve the opt out notice and specify in accordance with sub-paragraphs (3) and (4) the date on which the temporary opt out is to commence and the date that it is to come to an end (“the end date”); or

(b) reject the opt out notice in accordance with sub-paragraph (2),

and shall notify the contractor of its decision as soon as possible, including reasons for its decision.

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- (2) A Health Board may reject the opt out notice on the ground that the contractor—
 - (a) is providing additional services to patients other than its own registered patients or enhanced services; or
 - (b) has no reasonable need temporarily to opt out having regard to its ability to deliver the additional service.
- (3) The date specified by the Health Board for the commencement of the temporary opt out shall wherever reasonably practicable be the date requested by the contractor in its opt out notice.
- (4) Before determining the end date, the Health Board shall make reasonable efforts to reach agreement with the contractor.
- (5) Where the Health Board approves an opt out notice, the contractor's obligation to provide the additional service specified in the notice shall be suspended from the date specified by the Health Board in its decision under sub-paragraph (1), and shall remain suspended until the end date unless—
 - (a) the contractor and the Health Board agree in writing an earlier date, in which case the suspension shall come to an end on the earlier date agreed;
 - (b) the Health Board specifies a later date under sub-paragraph (6), in which case the suspension shall end on the later date specified;
 - (c) sub-paragraph (7) applies and the contractor refers the matter to the NHS dispute resolution procedure (or, where applicable in the case of a non-NHS contract, commences court proceedings), in which case the suspension shall end—
 - (i) where the outcome of the dispute is to uphold the decision of the Health Board, on the day after the date of the decision of the adjudicator or, as the case may be, the court;
 - (ii) where the outcome of the dispute is to overturn the decision of the Health Board 28 days after the decision of the adjudicator or, as the case may be, the court; or
 - (iii) where the contractor ceases to pursue the NHS dispute resolution procedure or, as the case may be, court proceedings, on the day after the date that the contractor withdraws its claim or the procedure is or proceedings are otherwise terminated by the adjudicator or the court;
 - (d) sub-paragraph (9) applies and—
 - (i) the Health Board refuses the contractor's request for a permanent opt out within the period of 28 days ending with the end date, in which case the suspension shall come to an end 28 days after the end date;
 - (ii) the Health Board refuses the contractor's request for a permanent opt out after the end date, in which case the suspension shall come to an end 28 days after the date of service of the notice; or
 - (iii) the Health Board notifies the contractor after the end date that the assessment panel has not approved its proposed decision to refuse the contractor's request to opt out permanently under sub-paragraph (16), in which case the suspension shall come to an end 28 days after the date of service of the notice under that paragraph.
- (6) Before the end date, a Health Board may, in exceptional circumstances and with the agreement of the contractor, notify the contractor in writing of a later date on which the temporary opt out is to come to an end, being a date no more than six months later than the end date.
- (7) Where the Health Board considers that—
 - (a) the contractor will be unable to satisfactorily provide the additional service at the end of the temporary opt out; and

- (b) it would not be appropriate to exercise its discretion under sub-paragraph (6) to specify a later date on which the temporary opt out is to come to an end or the contractor does not agree to a later date;

the Health Board may notify the contractor in writing at least 28 days before the end date that a permanent opt out shall follow a temporary opt out.

(8) Where a Health Board notifies the contractor under sub-paragraph (7) that a permanent opt out shall follow a temporary opt out, the permanent opt out shall take effect immediately after the end of the temporary opt out.

(9) A contractor who has temporarily opted out may, at least three months prior to the end date, notify the Health Board in writing that it wishes to opt out permanently of the additional service in question.

(10) Where the contractor has notified the Health Board under sub-paragraph (9) that it wishes to opt out permanently, the temporary opt out shall be followed by a permanent opt out beginning on the day after the end date unless the Health Board refuses the contractor's request to opt out permanently by giving notice in writing to the contractor to this effect.

(11) A Health Board may only give a notice under sub-paragraph (10) with the approval of the assessment panel.

(12) The Health Board must ensure that an assessment panel is appointed by another Health Board as soon as is practicable to consider and determine whether or not to approve the Health Board's proposed decision to refuse a permanent opt out.

(13) The Health Board shall provide the assessment panel with such information as the assessment panel may reasonably require to enable it to reach a determination.

(14) Where a Health Board seeks the approval of the assessment panel to a proposed decision to refuse a permanent opt out, it shall notify the contractor of having done so.

(15) If the assessment panel has not reached a decision as to whether or not to approve the Health Board's proposed decision to refuse a permanent opt out before the end date, the contractor's obligation to provide the additional service shall remain suspended until the date specified in sub-paragraph (5)(d)(ii) or (iii) (whichever is applicable).

(16) Where after the end date the assessment panel notifies the Health Board that it does not approve the Health Board's proposed decision to refuse a permanent opt out, the Health Board shall notify the contractor in writing of this fact as soon as is reasonably practicable.

(17) A temporary opt out or permanent opt out commences, and a temporary opt out ends, at 08.00 on the relevant day unless—

- (a) the day is not a working day, in which case the opt out shall take effect on the next working day at 08.00; or
(b) the Health Board and the contractor agree a different day or time.

(18) Any decision or determination by the assessment panel for the purposes of this paragraph may be reached by a majority.

Permanent opt outs

3.—(1) In this paragraph—

“A day” is the day specified by the contractor in its permanent opt out notice to a Health Board for the commencement of the permanent opt;

“B day” is the day six months after the date of service of the permanent opt out notice; and

“C day” is the day nine months after the date of service of the permanent opt out notice.

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(2) As soon as is reasonably practicable and in any event within the period 28 days beginning with the date of receipt of a permanent opt out notice under paragraph 1(5) (or temporary opt out notice which is treated as a permanent opt out notice under paragraph 1(7)), the Health Board shall—

- (a) approve the opt out notice; or
- (b) reject the opt out notice in accordance with sub-paragraph (3),

and shall notify the contractor of its decision as soon as possible, including reasons for its decision, where its decision is to reject the opt out notice.

(3) A Health Board may reject the opt out notice on the ground that the contractor is providing an additional service to patients other than its registered patients or enhanced services.

(4) A contractor may not withdraw an opt out notice once it has been approved by the Health Board in accordance with sub-paragraph (2)(a) without the Health Board's agreement.

(5) If the Health Board approves the opt out notice under sub-paragraph (2)(a), it shall use its reasonable endeavours to make arrangements for the contractor's registered patients to receive the additional service from an alternative provider from A day.

(6) The contractor's duty to provide the additional service shall terminate on A day unless the Health Board serves a notice under sub-paragraph (7) (extending A day to B day or C day).

(7) If the Health Board is not successful in finding an alternative provider to take on the provision of the additional service from A day, then it shall notify the contractor in writing of this fact not later than one month before A day, and—

- (a) in a case where A day is three months after service of the opt out notice, the contractor shall continue to provide the additional service until B day unless at least one month before B day the contractor receives a notice in writing from the Health Board under sub-paragraph (8) that despite using its reasonable endeavours, it has failed to find an alternative provider to take on the provision of the additional service from B day;
- (b) in a case where A day is six months after the service of the opt out notice, the contractor shall continue to provide the additional service until C day unless at least one month before C day it receives a notice from the Health Board under sub-paragraph (11) that it has made an application to assessment panel under sub-paragraph (10) seeking approval of the assessment panel to a decision to refuse a permanent opt out or to delay the commencement of a permanent opt out until after C day.

(8) Where in accordance with sub-paragraph (7)(a) the permanent opt out is to commence on B day and the Health Board, despite using its reasonable endeavours, has failed to find an alternative provider to take on the provision of the additional service from that day, it shall notify the contractor in writing of this fact at least one month before B day, in which case the contractor shall continue to provide the additional service until C day unless at least one month before C day it receives a notice from the Health Board under sub-paragraph (11) that it has applied to the assessment panel under sub-paragraph (10) seeking the approval of the assessment panel to a decision to refuse a permanent opt out or to postpone the commencement of a permanent opt out until after C day.

(9) As soon as is reasonably practicable and in any event within 7 days of the Health Board serving a notice under sub-paragraph (8), the Health Board shall enter into discussions with the contractor concerning the support that the Health Board may give to the contractor or other changes which the Health Board or the contractor may make in relation to the provision of the additional service until C day.

(10) A Health Board may, if it considers that there are exceptional circumstances, make an application to the assessment panel for approval of a decision to—

- (a) refuse a permanent opt out; or
- (b) postpone the commencement of a permanent opt out until after C day.

(11) As soon as practicable after making an application under sub-paragraph (10) to the assessment panel, the Health Board shall notify the contractor in writing that it has made such an application.

(12) The Health Board must ensure that an assessment panel is appointed by another Health Board as soon as is practicable to consider and determine whether or not to approve the Health Board's proposed decision to refuse a permanent opt out or to postpone the commencement of a permanent opt out until after C day.

(13) The Health Board shall provide the assessment panel with such information as the assessment panel may reasonably require to enable it to reach a determination.

(14) On receiving an application under sub-paragraph (10) for approval of a decision to refuse a permanent opt out, the assessment panel shall—

- (a) approve the Health Board's application;
- (b) reject the Health Board's application, but nonetheless recommend a different date for the commencement of the permanent opt out which may be later than C day; or
- (c) reject the Health Board's application.

(15) On receiving an application under sub-paragraph (10) for approval of a decision to postpone the commencement of a permanent opt out until after C day, the assessment panel shall—

- (a) approve the Health Board's application;
- (b) reject the Health Board's application, but nonetheless recommend—
 - (i) that the permanent opt out commence on an earlier date to that proposed by the Health Board in its application, or
 - (ii) that the permanent opt out be refused; or
- (c) reject the Health Board's application.

(16) The assessment panel shall notify the Health Board and the contractor in writing of its decision under sub-paragraph (14) or (15) as soon as is practicable, including reasons for its decision.

(17) Where the assessment panel—

- (a) approves a decision to refuse an opt out under sub-paragraph (14)(a); or
- (b) recommends that a permanent opt out be refused under sub-paragraph (15)(b)(ii),

the Health Board shall notify the contractor in writing that the contractor may not opt out of the additional service.

(18) Where a Health Board notifies a contractor under sub-paragraph (17), the contractor may not serve a preliminary opt out notice in respect of that additional service for a period of twelve months beginning with the date of service of the Health Board's notice under sub-paragraph (17) unless there has been a change in the circumstances of the contractor in relation to its ability to deliver services under the contract.

(19) Where the assessment panel—

- (a) recommends a different date for the commencement of the permanent opt out under sub-paragraph (14)(b);
- (b) approves a Health Board's application to postpone a permanent opt out under sub-paragraph (15)(a); or
- (c) recommends an earlier date to that proposed by the Health Board in its application under sub-paragraph (15)(b)(i),

the Health Board shall in accordance with the decision of the assessment panel notify the contractor in writing of its decision and the notice shall specify the date of the commencement of the permanent opt out.

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(20) Where the assessment panel rejects the Health Board's application under sub-paragraph (14) (c) or (15)(c), the Health Board shall notify the contractor in writing that there shall be a permanent opt out, and the permanent opt out shall commence on C day or 28 days after the date of service of the Health Board's notice, whichever is the later.

(21) If the assessment panel has not reached a decision on the Health Board's application under sub-paragraph (10) before C day, the contractor's obligation to provide the additional service shall continue until a notice is served on the contractor by the Health Board under sub-paragraph (19) or (20).

(22) Nothing in sub-paragraphs (1) to (21) above shall prevent the contractor and the Health Board from agreeing a different date for the termination of the contractor's duty under the contract to provide the additional service and, accordingly, varying the contract in accordance with paragraph 94(1) of Schedule 5.

(23) The permanent opt out takes effect at 08.00 on the relevant day unless—

- (a) the day is not a working day, in which case the opt out shall take effect on the next working day at 08.00; or
- (b) the Health Board and the contractor agree a different day or time.

(24) Any decision or determination by the assessment panel for the purposes of this paragraph may be reached by a majority.

Out of hour opt outs where the opt out notice is served after 30th September 2004

4.—(1) This paragraph applies where a contractor wishes to serve or serves an out of hours opt out notice after 30th September 2004.

(2) A contractor which wishes to terminate its obligation to provide out of hours services which was included in the contract pursuant to regulation 30 shall notify the relevant Health Board in writing to that effect ("an out of hours opt out notice").

(3) An out of hours opt out notice shall specify the date from which the contractor would like the opt out to take effect, which must be at least three or six months after the date of service of the out of hours opt out notice.

(4) As soon as is reasonably practicable and in any event within 28 days of receiving the out of hours opt out notice, the Health Board shall approve the notice and specify in accordance with sub-paragraph (6) the date on which the out of hours opt out is to commence ("OOH day").

(5) The Health Board shall notify the contractor of its decision as soon as possible.

(6) The date specified in sub-paragraph (4) shall be the date specified in the out of hours opt out notice.

(7) A contractor may not withdraw an out of hours opt out notice once it has been approved by the Health Board under sub-paragraph (4), without the Health Board's agreement.

(8) Following receipt of the out of hours opt out notice, the Health Board must use its reasonable endeavours to make arrangements for the contractor's registered patients to receive the out of hours services from an alternative provider from OOH day.

(9) Sub-paragraphs (6) to (24) of paragraph 3 shall apply to an out of hours opt out as they apply to a permanent opt out and as if the reference to "A day" was a reference to "OOH day" and the reference in paragraph 3(18) to a "permanent opt out notice" was a reference to "an out of hours opt out notice".

Out of hours opt out where opt out notice is served before 1st October 2004

5.—(1) This paragraph shall apply where a contractor wishes to serve or serves an out of hours opt out notice before 1st October 2004.

(2) In this paragraph—

“OOH day” is the day specified by the Health Board for the commencement of the out of hours opt out in its decision under sub-paragraph (5);

“OOHB day” is the day six months after the date of service of the out of hours opt out notice; and

“OOHC day” is the day specified by the Health Board in its decision under sub-paragraph (11) or (13) (which must be nine months after the date of service of the out of hours opt out notice or before 2nd January 2005).

(3) A contractor which wishes to terminate its obligation to provide out of hours services which was included in the contract pursuant to regulation 30 shall notify the Health Board in writing to that effect (“an out of hours opt out notice”).

(4) An out of hours opt out notice shall state the date on which the contractor would like the opt out to take effect, which must be either three or six months after the date of service of the out of hours opt out notice.

(5) As soon as is reasonably practicable and in any event within 28 days of receiving the out of hours opt out notice, the Health Board shall approve the notice and specify in accordance with sub-paragraphs (6) and (7) the date on which the out of hours opt out is to commence (“OOH day”) and the Health Board shall notify the contractor in writing of its decision as soon as possible, including reasons for its decision.

(6) Subject to sub-paragraph (7), OOH day shall be—

(a) the date specified in the out of hours opt out notice; or

(b) any other date before 2nd January 2005.

(7) A Health Board may not specify under sub-paragraph (5) a date earlier than the date specified in the out of hours opt out notice.

(8) A contractor may not withdraw an out of hours opt out notice once it has been approved by a Health Board under sub-paragraph (5) without the Health Board’s agreement.

(9) Following receipt of the out of hours opt out notice, the Health Board must use its reasonable endeavours to make arrangements for the contractor’s registered patients to receive the out of hours services from an alternative provider from OOH day.

(10) The contractor’s duty to provide the out of hours services shall terminate on OOH day unless the Health Board—

(a) serves notice under sub-paragraph (11) (extending OOH day to OOHB day or OOHC day); or

(b) makes an application under sub-paragraph (14) (seeking the approval of the assessment panel to a decision to refuse an opt out or to delay the taking of effect of an opt out until after OOH day).

(11) If the Health Board is not successful in finding an alternative provider to take on the provision of the out of hours services from OOH day, then it shall notify the contractor in writing of this fact no later than one month before OOH day, and—

(a) in a case where OOH day is three months after service of the out of hours opt out notice, the contractor shall continue to provide the out of hours services until OOHB day unless at least one month before OOHB day the contractor receives a notice in writing from the Health Board under sub-paragraph (13) that despite using its reasonable endeavours, the

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Board has failed to find an alternative provider to take on the provision of the out of hours services from OOHB day;

- (b) in a case where OOH day is after the day three months after the service of the out of hours opt out notice, the contractor shall continue to provide the out of hours services until OOHC day (which shall be specified by the Health Board in accordance with sub-paragraph (12) and included in its notice to the contractor under this sub-paragraph) unless at least one month before OOHC day the contractor receives a notice from the Health Board under sub-paragraph (16) that it has made an application to the assessment panel under sub-paragraph (14) seeking the panel's approval to a decision to refuse an opt out or to delay the commencement of the opt out until after OOHC day.

(12) OOHC day shall be any day before 2nd January 2005 or the day nine months after the service of the out of hours opt out notice.

(13) Where in accordance with sub-paragraph (11)(a) the out of hours opt out is to commence on OOHB day and the Health Board, despite using its reasonable endeavours has failed to find an alternative provider to take on the provision of the out of hours services from that day, it shall notify the contractor in writing of this fact at least one month before OOHB day, in which case the contractor shall continue to provide the out of hours service until OOHC day (which shall be specified by the Health Board in accordance with sub-paragraph (12) and included in its notice to the contractor under this sub-paragraph) unless at least one month before OOHC day the contractor receives a notice from the Health Board under sub-paragraph (16) that it has applied to the assessment panel under sub-paragraph (14) seeking the approval of the assessment panel to a decision to refuse an opt out or to postpone the commencement of an opt out until after OOHC day.

(14) The Health Board may, if it considers there are exceptional circumstances, make an application to the assessment panel for approval of a decision to—

- (a) refuse an opt out; or
- (b) postpone the commencement of an opt out until after—
 - (i) OOHC day, or
 - (ii) OOH day where OOH day is 1st January 2005 and 1st January 2005 is nine months or more after the date of the out of hours opt out notice.

(15) Where OOH day is 1st January 2005, and 1st January 2005 is nine months or more after the date of the out of hours opt out notice, an application under sub-paragraph (14) shall be made at least one month before OOH day.

(16) As soon as practicable after making an application under sub-paragraph (14) to the assessment panel, the Health Board shall notify the contractor in writing that it has made such an application.

(17) Sub-paragraphs (12) to (24) of paragraph 3 shall apply to an out of hours opt out as they apply to a permanent opt out and as if the reference to "C day" was a reference to OOHC day or OOH day where OOH day is 1st January 2005 and 1st January 2005 is nine months or more after the date of the out of hours opt out notice.

Informing patients of opt-outs

6.—(1) Prior to any opt out taking effect, the Health Board and the contractor shall discuss how to inform patients of the proposed opt out.

(2) The contractor shall, if requested by the Health Board inform the contractor's registered patients of an opt out and the arrangements made for them to receive the additional service or out of hours services by—

- (a) placing a notice in the practice's waiting room; or

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(b) including the information in the practice leaflet.

(3) In this paragraph “opt out” means an out of hours opt out, a permanent opt out or a temporary opt out.

SCHEDULE 3

Regulation 21

LIST OF PRESCRIBED MEDICAL CERTIFICATES

<i>Description of medical certificate</i>	<i>Enactment under or for the purpose of which certificate required</i>
1. To support a claim or to obtain payment either personally or by proxy; to prove incapacity to work or for self-support for the purposes of an award by the Secretary of State; or to enable proxy to draw pensions etc.	Naval and Marine Pay and Pensions Act 1865 (3)
	Air Force (Constitution) Act 1917 (4)
	Pensions (Navy, Army, Air Force and Mercantile Marine) Act 1939 (5)
	Personal Injuries (Emergency Provisions) Act 1939 (6)
	Pensions (Mercantile Marine) Act 1942 (7)
	Polish Resettlement Act 1947 (8)
	Social Security Administration Act 1992 (9)
	Social Security Contributions and Benefits Act 1992 (10)
	Social Security Act 1998 (11)
	2. To establish pregnancy for the purpose of obtaining welfare foods.
3. To secure registration of still-birth.	Section 21 of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (special provision as to registration of still-birth) (13)

(3) 1865 c. 73.

(4) 1917 c. 51.

(5) 1939 c. 83.

(6) 1939 c. 82.

(7) 1942 c. 26.

(8) 1947 c. 19.

(9) 1992 c. 5.

(10) 1992 c. 4.

(11) 1998 c. 14.

(12) 1988 c. 7. Section 13 was amended by the Social Security Act 1990 (c. 27), Schedule 5, paragraph 8(11)(a), and the Social Security (Consequential Provisions) Act 1992 (c. 6), Schedule 1, paragraph 94.

(13) 1965 c. 49. Section 21 was amended by the Nurses, Midwives and Health Visitors Act 1979 (c. 36), Schedule 6, paragraphs 12 and 13.

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<i>Description of medical certificate</i>	<i>Enactment under or for the purpose of which certificate required</i>
4. To enable payment to be made to an institution or other person in case of mental disorder of persons entitled to payment from public funds.	Section 142 of the Mental Health Act 1983 (pay, pensions etc. of mentally disordered persons)(14)
5. To establish unfitness for jury service.	Criminal Procedure (Scotland) Act 1995(15) Court Of Session Act 1988(16)
6. To support late application for reinstatement in civil employment or notification of non-availability to take up employment owing to sickness.	Reserve Forces (Safeguarding of Employment) Act 1985(17)
7. To enable a person to be registered as an absent voter on grounds of physical incapacity.	Representation of the People Act 1983(18)
8. To support applications for certificates conferring exemption from charges in respect of drugs, medicines and appliances.	National Health Service (Scotland) Act 1978(19)
9. To support a claim by or on behalf of a severely mentally impaired person for exemption from liability to pay the Council Tax or eligibility for a discount in respect of the amount of Council Tax payable.	Local Government Finance Act 1992(20), Schedule 1, paragraph 2(1)(b)

SCHEDULE 4

Regulation 24

FEES AND CHARGES

1. The contractor may demand or accept a fee or other remuneration—
 - (a) from any statutory body for services rendered for the purposes of that body's statutory functions;
 - (b) from any body, employer or school for a routine medical examination of persons for whose welfare the body, employer or school is responsible, or an examination of such persons for the purpose of advising the body, employer or school of any administrative action they might take;
 - (c) for treatment which is not primary medical services or otherwise required to be provided under the contract and which is given—
 - (i) pursuant to the provisions of section 57 of the Act(**21**) (accommodation and services for private patients), or

(14) 1983 c. 20. Section 142 was amended by S.I. 1999/1820.

(15) 1995 c. 46.

(16) 1988 c. 36.

(17) 1985 c. 17.

(18) 1983 c. 2.

(19) 1978 c. 29.

(20) 1992 c. 14.

(21) 1978 c. 29. Section 57 was substituted by the Health and Medicines Act 1988 (c. 49), section 7 and amended by the National Health Service and Community Care Act 1990 (c. 19), Schedule 9, paragraph 19.

- (ii) in accommodation provided by a care home service which is not providing services under the Act,
if, in either case, the person providing the treatment is serving on the staff of a hospital providing services under the Act as a specialist providing treatment of the kind the patient requires and if, within 7 days of giving the treatment, the contractor or the person providing the treatment supplies the Health Board, on a form provided by it for the purpose, with such information about the treatment as it may require;
- (d) under section 158 of the Road Traffic Act 1988 (payment for emergency treatment of traffic casualties)**(22)**;
- (e) when the contractor treats a patient under regulation 24(3), in which case the contractor shall be entitled to demand and accept a reasonable fee (recoverable in certain circumstances under regulation 24(4)) for any treatment given, if the contractor gives the patient a receipt;
- (f) for attending and examining (but not otherwise treating) a patient—
 - (i) at the patient’s request at a police station in connection with possible criminal proceedings against the patient,
 - (ii) at the request of a commercial, educational or not-for-profit organisation for the purpose of creating a medical report or certificate,
 - (iii) for the purpose of creating a medical report required in connection with an actual or potential claim for compensation by the patient;
- (g) for treatment consisting of an immunisation for which no remuneration is payable by the Health Board and which is requested in connection with travel abroad;
- (h) for prescribing or providing drugs, medicines or appliances (including a collection of such drugs, medicines and appliances in the form of a travel kit) which a patient requires to have in his possession solely in anticipation of the onset of an ailment or occurrence of an injury while he is outside the United Kingdom but for which he is not requiring treatment when the medicine is prescribed;
- (i) for a medical examination—
 - (i) to enable a decision to be made whether or not it is inadvisable on medical grounds for a person to wear a seat belt, or
 - (ii) for the purpose of creating a report—
 - (aa) relating to a road traffic accident or criminal assault, or
 - (bb) that offers an opinion as to whether a patient is fit to travel;
- (j) for testing the sight of a person to whom none of the paragraphs (a), (b) or (c) of section 26(1) of the Act**(23)** (arrangements for general ophthalmic services) applies (including by reason of regulations under section 26(1E)**(24)**) of the Act;
- (k) where the contractor is authorised or required by a Health Board under the contract in accordance with paragraph 44 of Schedule 5 to provide drugs, medicines or appliances to a patient and provides for that patient, otherwise than by way of pharmaceutical services, any Scheduled drug; and
- (l) for prescribing or providing drugs or medicines for malaria chemoprophylaxis.

(22) 1988 c. 52. Section 158 was amended by S.I. 1995/889, Article 3.

(23) Section 26(1) was amended by the Health and Social Security Act 1984 (c. 48), Schedule 1, paragraph 1 and the Health and Medicines Act 1988 (c. 49), section 13(4).

(24) Section 26(1E) was inserted by the Health and Medicines Act 1988 (c. 49), section 13(4).

SCHEDULE 5

Regulation 26

OTHER CONTRACTUAL TERMS

PART 1

Provision of Services

Premises

1. Subject to any plan which is included in the contract pursuant to regulation 18(3), the contractor shall ensure that the premises used for the provision of services under the contract are—

- (a) suitable for the delivery of those services; and
- (b) sufficient to meet the reasonable needs of the contractor's patients.

Attendance at practice premises

2.—(1) The contractor shall take steps to ensure that any patient who—

- (a) has not previously made an appointment; and
- (b) attends at the practice premises during the normal hours for essential services,

is provided with such services by an appropriate health care professional during that surgery period except in the circumstances specified in sub-paragraph (2).

(2) The circumstances referred to in sub-paragraph (1) are that—

- (a) it is more appropriate for the patient to be referred elsewhere for services under the Act; or
- (b) the patient is then offered an appointment to attend again within a time which is appropriate and reasonable having regard to all the circumstances and the patient's health would not thereby be jeopardised.

Attendance outside practice premises

3.—(1) In the case of a patient whose medical condition is such that in the reasonable opinion of the contractor—

- (a) attendance on the patient is required; and
- (b) it would be inappropriate for the patient to attend at the practice premises,

the contractor shall provide services to that patient at whichever in its judgement is the most appropriate of the places set out in sub-paragraph (2).

(2) The places referred to in sub-paragraph (1) are—

- (a) the place recorded in the patient's medical records as being the patient's last home address;
- (b) such other place as the contractor has informed the patient and the Health Board is the place where the contractor has agreed to visit and treat the patient; or
- (c) some other place in the contractor's practice area.

(3) Nothing in this paragraph prevents the contractor from—

- (a) arranging for the referral of a patient without first seeing the patient, in a case where the medical condition of that patient makes that course of action appropriate; or
- (b) visiting the patient in circumstances where this paragraph does not place it under an obligation to do so.

Newly registered patients

- 4.—(1) Where a patient has been—
- (a) accepted on a contractor’s list of patients under paragraph 15; or
 - (b) assigned to that list by the Health Board,

the contractor shall, in addition to and without prejudice to its other obligations in respect of that patient under the contract, invite the patient to participate in a consultation either at the contractor’s practice premises or, if the medical condition of the patient so warrants, at one of the places referred to in paragraph 3(2).

(2) An invitation under sub-paragraph (1) shall be issued within six months of the date of the acceptance of the patient on, or their assignment to, the contractor’s list.

(3) Where a patient (or, where appropriate, in the case of a patient who is a child, the child’s parent) agrees to participate in a consultation mentioned in sub-paragraph (1) the contractor shall, in the course of that consultation make such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances.

Patients not seen within 3 years

- 5.—(1) Where a registered patient who—
- (a) has attained the age of 16 years but has not attained the age of 75 years; and
 - (b) has attended neither a consultation with, nor a clinic provided by, the contractor within the preceding 3 years prior to the date of the patient’s request,

requests a consultation the contractor shall, in addition and without prejudice to the contractor’s other obligations in respect of that patient under the contract, provide such a consultation in the course of which the contractor shall make such inquiries and undertake such examinations as appear to the contractor to be appropriate in all the circumstances.

Patients aged 75 years and over

- 6.—(1) Where a registered patient who—
- (a) has attained the age of 75 years; and
 - (b) has not participated in a consultation under this paragraph within the period of twelve months prior to the date of the patient’s request,

requests a consultation, the contractor shall, in addition and without prejudice to its other obligations in respect of that patient under the contract, provide such a consultation in the course of which it shall make such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances.

(2) A consultation under sub-paragraph (1) shall take place in the home of the patient where, in the reasonable opinion of the contractor, it would be inappropriate, as a result of the patient’s medical condition, for the patient to attend at the practice premises.

Clinical reports

7.—(1) Where the contractor provides any clinical services, other than under a private arrangement, to a patient who is not on the contractor’s list of patients, the contractor shall, as soon as reasonably practicable, provide a clinical report relating to the consultation, and any treatment provided, to the Health Board.

- (2) The Health Board shall send any report received under sub-paragraph (1)—

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- (a) to the person with whom the patient is registered for the provision of essential services or their equivalent; or
- (b) if the person referred to in paragraph (a) is not known to it, to the Health Board in whose area the patient is resident.

Storage of vaccines

8. The contractor shall ensure that—
- (a) all vaccines are stored in accordance with the manufacturer's instructions; and
 - (b) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken on all working days.

Infection control

9. The contractor shall ensure that it has appropriate arrangements for infection control and decontamination.

Criteria for out of hours services

10. A contractor whose contract includes the provision of out of hours services shall only be required to provide such services if, in the reasonable opinion of the contractor in the light of the patient's medical condition, it would not be reasonable in all the circumstances for the patient to wait for the services required until the next time at which the patient could obtain such services during core hours.

Standards for out of hours services

11. From 1st January 2005, a contractor which provides out of hours services must, in the provision of such services, meet the quality standards set out from time to time in guidance which has been issued to Health Boards by NHS Quality Improvement Scotland and notified in writing to the contractor by the Health Board.

Duty of co-operation in relation to additional, enhanced and out of hours services

12.—(1) A contractor which does not provide to its registered patients or to persons whom it has accepted as temporary residents—

- (a) a particular additional service;
- (b) a particular enhanced service; or
- (c) out of hours services, either at all or in respect of some periods or some services,

shall comply with the requirements specified in sub-paragraph (2).

- (2) The requirements referred to in sub-paragraph (1) are that the contractor shall—
- (a) co-operate, insofar as it is reasonable, with any person responsible for the provision of that service or those services;
 - (b) comply in core hours with any reasonable request for information from such a person or from the Health Board relating to the provision of that service or those services; and
 - (c) in the case of out of hours services, take reasonable steps to ensure that any patient who contacts the practice premises during the out of hours period is provided with information about how to obtain services during that period.

(3) Nothing in this paragraph shall require a contractor whose contract does not include the provision of out of hours services to make itself available during the out of hours period.

Duty of co-operation in relation to additional, enhanced and out of hours services

13. Where a contractor is to cease to be required to provide to its patients—
- (a) a particular additional service;
 - (b) a particular enhanced service; or
 - (c) out of hours services, either at all or in respect of some periods or some services;

it shall comply with any reasonable request for information relating to the provision of that service or those services made by the Health Board or by any person with whom the Board intends to enter into a contract for the provision of such services.

PART 2

Patients

List of patients

14. The Health Board shall prepare and keep up to date a list of the patients—
- (a) who have been accepted by the contractor for inclusion in its list of patients under paragraph 15 and who have not subsequently been removed from that list under paragraphs 19 to 27; and
 - (b) who have been assigned to the contractor under paragraph 32 or 33 and whose assignment has not subsequently been rescinded.

Application for inclusion in a list of patients

15.—(1) The contractor may, if its list of patients is open, accept an application for inclusion in its list of patients made by or on behalf of any person whether or not resident in its practice area or included, at the time of that application, in the list of patients of another contractor or provider of primary medical services.

(2) The contractor may, if its list of patients is closed, only accept an application for inclusion in its list of patients from a person who is an immediate family member of a registered patient whether or not resident in its practice area or included, at the time of that application, in the list of patients of another contractor or provider of primary medical services.

(3) Subject to sub-paragraph (4), an application for inclusion in a contractor's list of patients shall be made by delivering to the practice premises a medical card or an application signed (in either case) by the applicant or a person authorised by the applicant to sign on the applicant's behalf.

- (4) An application may be made—
- (a) on behalf of any child—
 - (i) by either parent, or in the absence of both parents, the guardian or other adult person who has care of the child,
 - (ii) by a person duly authorised by a local authority, where the child is in the care of a local authority under the Children (Scotland) Act 1995(25); or
 - (iii) by a person duly authorised by a voluntary organisation, by which the child is being accommodated under the provisions of that Act; or
 - (b) on behalf of any adult who is incapable of making such an application, or authorising such an application to be made on their behalf, by the primary carer of that person or by the

(25) 1995 c. 36.

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person authorised under the Adults with Incapacity (Scotland) Act 2000(26) to act on the patient's behalf.

(5) A contractor which accepts an application for inclusion in its list of patients shall notify the Health Board in writing as soon as possible.

(6) On receipt of a notice under sub-paragraph (5), the Health Board shall-

- (a) include that person in the contractor's list of patients from the date on which the notice is received; and
- (b) notify the applicant (or, in the case of a child or incapable adult, the person making the application on their behalf) of the acceptance.

Temporary residents

16.—(1) The contractor may, if its list of patients is open, accept a person as a temporary resident provided it is satisfied that the person is—

- (a) temporarily resident away from the person's normal place of residence and is not being provided with essential services (or their equivalent) under any other arrangement in the locality where the person is temporarily residing; or
- (b) moving from place to place and not for the time being resident in any place.

(2) For the purposes of sub-paragraph (1), a person shall be regarded as temporarily resident in a place if, when the person arrives in that place, the person intends to stay there for more than 24 hours but not more than three months.

(3) A contractor which wishes to terminate its responsibility for a person accepted as a temporary resident before the end of—

- (a) three months; or
- (b) such shorter period for which it agreed to accept the person as a patient,

shall notify the person either orally or in writing and its responsibility for that patient shall cease 7 days after the date on which the notification was given.

(4) At the end of three months, or on such earlier date as its responsibility for the temporary resident has come to an end, the contractor shall notify the Health Board in writing of any person whom it accepted as a temporary resident.

Refusal of application for inclusion in the list of patients or for acceptance as a temporary resident

17.—(1) The contractor shall only refuse an application made under paragraph 15 or 16 if it has reasonable grounds for doing so which do not relate to the applicant's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition.

(2) The reasonable grounds referred to in paragraph (1) shall, in the case of applications made under paragraph 15, include the ground that the applicant does not live in the contractor's practice area.

(3) A contractor which refuses an application made under paragraph 15 or 16 shall, within 14 days of its decision, notify the applicant (or, in the case of a child or incapable adult, the person making the application on their behalf) in writing of the refusal and the reason for it.

(4) The contractor shall keep a written record of refusals of applications made under paragraph 15 and of the reasons for them and shall make this record available to the Health Board on request.

Patient preference of practitioner

18.—(1) Where the contractor has accepted an application for inclusion in its list of patients, it shall—

- (a) notify the patient (or, in the case of a child or incapable adult, the person who made the application on their behalf) of the patient's right to express a preference to receive services from a particular performer or class of performer either generally or in relation to any particular condition; and
- (b) record in writing any such preference expressed by or on behalf of the patient.

(2) The contractor shall endeavour to comply with any reasonable preference expressed under sub-paragraph (1) but need not do so if the preferred performer—

- (a) has reasonable grounds for refusing to provide services to the patient; or
- (b) does not routinely perform the service in question within the practice.

Removal from the list at the request of the patient

19.—(1) The contractor shall notify the Health Board in writing of any request for removal from its list of patients received from a registered patient.

(2) Where the Health Board—

- (a) receives notification from the contractor under sub-paragraph (1); or
- (b) receives a request from the patient to be removed from the contractor's list of patients,

it shall remove that person from the contractor's list of patients.

(3) A removal in accordance with sub-paragraph (2) shall take effect—

- (a) on the date on which the Health Board received notification of the registration of the person with another provider of essential services (or their equivalent); or
- (b) 14 days after the date on which the notification or request made under sub-paragraph (1) or (2) respectively is received by the Health Board,

whichever is the sooner.

(4) The Health Board shall, as soon as practicable, notify in writing—

- (a) the patient; and
- (b) the contractor,

that the patient's name will be or has been removed from the contractor's list of patients on the date referred to in sub-paragraph (3).

(5) In this paragraph and in paragraphs 20(1)(b) and (10), 21(6) and (7), 23 and 26, a reference to a request received from or advice, information or notification required to be given to a patient shall include a request received from or advice, information or notification required to be given to—

- (a) in the case of a patient who is a child, a parent or other person referred to in paragraph 15(4)(a); or
- (b) in the case of an adult patient who is incapable of making the relevant request or receiving the relevant advice, information or notification, a relative or the primary carer of the patient.

Removal from the list at the request of the contractor

20.—(1) Subject to paragraph 21, a contractor which has reasonable grounds for wishing a patient to be removed from its list of patients which do not relate to the applicant's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition shall—

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- (a) notify the Health Board in writing that it wishes to have the patient removed; and
 - (b) subject to sub-paragraph (2), notify the patient of its specific reasons for requesting removal.
- (2) Where, in the reasonable opinion of the contractor—
- (a) the circumstances of the removal are such that it is not appropriate for a more specific reason to be given; and
 - (b) there has been an irrevocable breakdown in the relationship between the patient and the contractor,
- the reason given under sub-paragraph (1) may consist of a statement that there has been such a breakdown.
- (3) Except in the circumstances described in sub-paragraph (4), a contractor may only request a removal under sub-paragraph (1) if, within the period of twelve months prior to the date of its request to the Health Board, it has warned the patient that the patient is at risk of removal and explained to him the reasons for this.
- (4) The circumstances referred to in sub-paragraph (3) are that—
- (a) the reason for the removal relates to a change of address;
 - (b) the contractor has reasonable grounds for believing that the issue of such a warning would—
 - (i) be harmful to the physical or mental health of the patient; or
 - (ii) put at risk the safety of the persons specified in sub-paragraph (5); or
 - (c) it is, in the opinion of the contractor, not otherwise reasonably practicable for a warning to be given.
- (5) The persons referred to in sub-paragraph (4) are—
- (a) in the case of a contract with an individual medical practitioner, that practitioner;
 - (b) in the case of a contract with a partnership, a partner in that partnership;
 - (c) in the case of a contract with a company, a legal and beneficial owner of shares in that company;
 - (d) a member of the contractor’s staff;
 - (e) a person engaged by the contractor to perform or assist in the performance of services under the contract; or
 - (f) any other person present—
 - (i) on the practice premises, or
 - (ii) in the place where services are being provided to the patient under the contract.
- (6) The contractor shall record in writing—
- (a) the date of any warning given in accordance with sub-paragraph (3) and the reasons for giving such a warning as explained to the patient; or
 - (b) the reason why no such warning was given.
- (7) The contractor shall keep a written record of removals under this paragraph which shall include—
- (a) the reason for removal given to the patient;
 - (b) the circumstances of the removal; and
 - (c) in cases where sub-paragraph (2) applies, the grounds for a more specific reason not being appropriate,

and shall make this record available to the Health Board on request.

(8) A removal requested in accordance with sub-paragraph (1) shall, subject to sub-paragraph (9) take effect from—

- (a) the date on which the Health Board receives notification of the registration of the person with another provider of essential services (or their equivalent); or
- (b) the eighth day after the Health Board receives the notice referred to in sub-paragraph (1) (a),

whichever is the sooner.

(9) Where, on the date on which the removal would take effect under sub-paragraph (8), the contractor is treating the patient at intervals of less than 7 days, the contractor shall notify the Health Board in writing of the fact and the removal shall take effect—

- (a) on the eighth day after the Health Board receives notification from the contractor that the person no longer needs such treatment; or
- (b) on the date on which the Health Board receives notification of the registration of the person with another provider of essential services (or their equivalent),

whichever is the sooner.

(10) The Health Board shall notify in writing—

- (a) the patient; and
- (b) the contractor,

that the patient's name has been or will be removed from the contractor's list of patients on the date referred to in sub-paragraph (8) or (9).

Removal from the list of patients who are violent

21.—(1) A contractor which wishes a patient to be removed from its list of patients with immediate effect on the grounds that—

- (a) the patient has committed an act of violence against any of the persons specified in sub-paragraph (2) or behaved in such a way that any such person has feared for that person's own safety; and
- (b) the contractor has reported the incident to the police or the Procurator Fiscal,

shall notify the Health Board in accordance with sub-paragraph (3).

(2) The persons referred to in sub-paragraph (1) are—

- (a) in the case of a contract with an individual medical practitioner, that practitioner;
- (b) in the case of a contract with a partnership, a partner in that partnership;
- (c) in the case of a contract with a company, a legal and beneficial owner of shares in that company;
- (d) a member of the contractor's staff;
- (e) a person engaged by the contractor to perform or assist in the performance of services under the contract; or
- (f) any other person present—
 - (i) on the practice premises or
 - (ii) in the place where services were provided to the patient under the contract.

(3) Notification under sub-paragraph (1) may be given by any means including telephone or fax but if not given in writing shall subsequently be confirmed in writing within 7 days (and for this purpose a faxed notification or transmission by electronic means is not a written one).

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(4) The Health Board shall acknowledge in writing receipt of a request from the contractor under sub-paragraph (1).

(5) A removal requested in accordance with sub-paragraph (1) shall take effect at the time that the contractor—

- (a) makes the telephone call to the Health Board; or
- (b) sends or delivers the notification to the Health Board.

(6) Where, pursuant to this paragraph, the contractor has notified the Health Board that it wishes to have a patient removed from the contractor's list of patients with immediate effect, it shall inform the patient concerned unless—

- (a) it is not reasonably practicable for it to do so; or
- (b) it has reasonable grounds for believing that to do so would—
 - (i) be harmful to the physical or mental health of the patient; or
 - (ii) put at risk the safety of one or more of the persons specified in sub-paragraph (2).

(7) Where the Health Board has removed a patient from the contractor's list of patients in accordance with sub-paragraph (5), it shall give written notice of the removal to that patient.

(8) Where a patient is removed from the contractor's list of patients in accordance with this paragraph, the contractor shall record in the patient's medical records that the patient has been removed under this paragraph and the circumstances leading to the patient's removal.

Removals from the list of patients registered elsewhere

22.—(1) The Health Board shall remove a patient from the contractor's list of patients if—

- (a) the patient has subsequently been registered with another provider of essential services (or their equivalent) in the area of the Health Board; or
- (b) it has received notice from another Health Board, Primary Care trust, Local Health Board, or a Health and Social Services Board that the patient has subsequently been registered with a provider of essential services (or their equivalent) outside the area of the Health Board.

(2) A removal in accordance with sub-paragraph (1) shall take effect—

- (a) on the date on which the Health Board receives notification of the registration of the person with the new provider; or
- (b) with the consent of the Health Board, on such other date as has been agreed between the contractor and the new provider.

(3) The Health Board shall notify the contractor in writing of patients removed from its list of patients under sub-paragraph (1).

Removals from the list of patients who have moved

23.—(1) Subject to sub-paragraph (2), where the Health Board is satisfied that a person on the contractor's list of patients has moved and no longer resides in that contractor's practice area, the Board shall—

- (a) inform that patient and the contractor that the contractor is no longer obliged to visit and treat the person;
- (b) advise the patient in writing either to obtain the contractor's agreement to the continued inclusion of the person on its list of patients or to apply for registration with another provider of essential services (or their equivalent); and

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- (c) inform the patient that if, after the expiration of 30 days from the date of the letter of advice mentioned in paragraph (b), the patient has not acted in accordance with the advice and informed the Board accordingly, the Health Board will remove the patient from the contractor's list of patients.

(2) If, at the expiration of the period of 30 days referred to in sub-paragraph (1)(c), the Health Board has not been notified of the action taken, it shall remove the patient from the contractor's list of patients and inform the patient and the contractor accordingly.

Removals from the list of patients who have moved

24. Where the address of a patient who is on the contractor's list of patients is no longer known to the Health Board, the Health Board shall—

- (a) give to the contractor notice in writing that it intends, at the end of the period of six months commencing with the date of the notice, to remove the patient from the contractor's list of patients; and
- (b) at the end of that period, remove the patient from the contractor's list of patients unless, within that period, the contractor satisfies the Health Board that it is still responsible for providing essential services to that patient.

Removals from the list of patients absent from the United Kingdom etc.

25.—(1) The Health Board shall remove a patient from the contractor's list of patients where it receives notification that that patient—

- (a) intends to be away from the United Kingdom for a period of at least three months;
- (b) is in Her Majesty's Forces;
- (c) has been absent from the United Kingdom for a period of more than three months; or
- (d) has died.

(2) A removal in accordance with sub-paragraph (1) shall take effect—

- (a) in the cases referred to in sub-paragraph (1)(a) and (b) from the date of the departure or enlistment or the date on which the Health Board first receives notification of the departure or enlistment, whichever is the later; or
- (b) in the cases referred to in sub-paragraph (1) (c) and (d) from the date on which the Health Board first receives notification of the absence or death.

(3) The Health Board shall notify the contractor in writing of patients removed from its list of patients under sub-paragraph (1).

Removals from the list of patients accepted elsewhere as temporary residents

26.—(1) The Health Board shall remove from the contractor's list of patients a patient who has been accepted as a temporary resident by another contractor or other provider of essential services (or their equivalent) where it is satisfied, after due inquiry—

- (a) that the person's stay in the place of temporary residence has exceeded three months; and
- (b) that the patient has not returned to the patient's normal place of residence or any other place within the contractor's practice area.

(2) The Health Board shall notify in writing of a removal under sub-paragraph (1)—

- (a) the contractor; and
- (b) where practicable, the patient.

(3) A notification to the patient under sub-paragraph (2)(b) shall inform the patient of—

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- (a) the patient's entitlement to make arrangements for the provision to the patient of essential services (or their equivalent), including by the contractor by which the patient has been treated as a temporary resident; and
- (b) the name and address of the Health Board in whose area the patient is resident.

Removals from the list of pupils etc. of a school

27.—(1) Where the contractor provides essential services under the contract to persons on the grounds that they are pupils at or staff or residents of a school, the Health Board shall remove from the contractor's list of patients any such persons who do not appear on particulars of persons who are pupils at or staff or residents of that school provided by that school.

(2) Where the Health Board has made a request to a school to provide the particulars mentioned in sub-paragraph (1) and has not received them, it shall consult the contractor as to whether it should remove from its list of patients any persons appearing on that list as pupils at, or staff or residents of, that school.

(3) The Health Board shall notify the contractor in writing of patients removed from its list of patients under sub-paragraph (1).

Termination of responsibility for patients not registered with the contractor

28.—(1) Where a contractor—

- (a) has received an application for the provision of medical services other than essential services—
 - (i) from a person who is not included in its list of patients, or
 - (ii) from a person whom the contractor has not accepted as a temporary resident, or
 - (iii) on behalf of a person mentioned in (i) or (ii) above, from one of the persons specified in paragraph 15(4); and
- (b) has accepted that person as a patient for the provision of the service in question,

its responsibility for that patient shall be terminated in one of the circumstances referred to in sub-paragraph (2).

(2) The circumstances referred to in sub-paragraph (1) are—

- (a) the patient informs the contractor that the patient no longer wishes it to be responsible for provision of the service in question;
- (b) in cases where the contractor has reasonable grounds for terminating its responsibility which do not relate to the person's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical condition, the contractor informs the patient that it no longer wishes to be responsible for providing the patient with the service in question; or
- (c) it comes to the notice of the contractor that the patient—
 - (i) no longer resides in the area for which the contractor has agreed to provide the service in question; or
 - (ii) is no longer included in the list of patients of another contractor to whose registered patients the contractor has agreed to provide that service.

(3) A contractor which wishes to terminate its responsibility for a patient under sub-paragraph (2) shall notify the patient of the termination and the reason for it.

(4) The contractor shall keep a written record of terminations under this paragraph and of the reasons for them and shall make this record available to the Health Board on request.

- (5) A termination under sub-paragraph (2)(b) shall take effect—
 - (a) from the date on which the notice is given where the grounds for termination are those specified in paragraph 21(1); or
 - (b) in all other cases, 14 days from the date on which the notice is given.

Closure of lists of patients

29.—(1) A contractor which wishes to close its list of patients shall notify the Health Board in writing to that effect.

(2) Within a period of 7 days beginning with the date of receipt of the notification referred to in sub-paragraph (1), or, if that is not reasonably practicable, as soon as is practicable thereafter, the Health Board shall enter into discussions with the contractor concerning the support which the Health Board may give the contractor, or other changes which the Health Board or the contractor may make, which would enable the contractor to keep its list of patients open.

(3) In the discussions referred to in sub-paragraph (2), both parties shall use reasonable endeavours to achieve the aim of keeping the contractor's list of patients open.

(4) The discussions mentioned in sub-paragraph (2) shall be completed within a period of 28 days beginning with the date of the Health Board's receipt of the notification referred to in sub-paragraph (1), or within such longer period as the parties may agree.

(5) If, following the discussions mentioned in sub-paragraph (2), the Health Board and the contractor reach agreement that the contractor's list of patients should remain open, the Health Board shall send full details of the agreement in writing to the contractor.

(6) The Health Board and the contractor shall comply with the terms of an agreement reached as mentioned in sub-paragraph (5).

(7) If, following the discussions mentioned in sub-paragraph (2)—

- (a) the Health Board and the contractor reach agreement that the contractor's list of patients should close; or
- (b) the Health Board and the contractor fail to reach agreement and the contractor still wishes to close the contractor's list of patients,

the contractor shall send a closure notice to the Health Board.

(8) A closure notice shall be submitted in the form specified in Schedule 7, and shall include the following details which (in a case falling within sub-paragraph (7)(a)) have been agreed between the parties or (in a case falling within sub-paragraph (7)(b)) are proposed by the contractor—

- (a) the period of time (which may not exceed twelve months) for which the contractor's list of patients will be closed;
- (b) the current number of the contractor's registered patients;
- (c) the number of registered patients (lower than the current number of such patients, and expressed either in absolute terms or as a percentage of the number of such patients specified pursuant to paragraph (b)) which, if that number were reached, would trigger the re-opening of the contractor's list of patients;
- (d) the number of registered patients (expressed either in absolute terms or as a percentage of the number of such patients specified pursuant to paragraph (b)) which, if that number were reached, would trigger the re-closure of the contractor's list of patients; and
- (e) any withdrawal or reduction in provision of any additional or enhanced services which had previously been provided under the contract.

(9) The Health Board shall forthwith acknowledge receipt of the closure notice in writing to the contractor.

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(10) Before the Health Board reaches a decision as to whether to approve or reject the closure notice under sub-paragraph (12), the Health Board and the contractor may enter into further discussions concerning the details of the closure notice as specified in sub-paragraph (8), with a view to reaching agreement; and, in particular, if the parties are unable to reach agreement regarding the period of time for which the contractor's list of patients will be closed, that period shall be twelve months.

(11) A contractor may not withdraw a closure notice for a period of three months beginning with the date on which the Health Board has received the notice, unless the Health Board has agreed otherwise in writing.

(12) Within a period of 14 days beginning with the date of receipt of the closure notice, the Health Board shall—

- (a) approve the closure notice; or
- (b) reject the closure notice,

and shall notify the contractor of its decision in writing as soon as possible.

(13) Approval of the closure notice under sub-paragraph (12)(a) includes approval of the details specified in accordance with sub-paragraph (8) (or, where those details are revised following discussions under sub-paragraph (10), approval of those details as so revised).

Approval of closure notice by the Health Board

30.—(1) If the Health Board approves the closure notice in accordance with paragraph 29(12)(a), the contractor shall close its list of patients—

- (a) with effect from a date agreed between the Health Board and the contractor; or
- (b) if no such agreement has been reached, with effect from the date on which the contractor receives notification of the Health Board's decision to approve the closure notice.

(2) Subject to sub-paragraph (3), the contractor's list of patients shall remain closed for the period specified in the closure notice in accordance with paragraph 29(8)(a) (or, where a period of twelve months has been fixed in accordance with paragraph 29(10), for that period).

(3) The contractor's list of patients shall re-open before the expiry of the period mentioned in sub-paragraph (2) if—

- (a) the number of the contractor's registered patients falls to the number specified in the closure notice in accordance with paragraph 29(8)(c); or
- (b) the Health Board and the contractor agree that the list of patients should re-open.

(4) If the contractor's list of patients has re-opened pursuant to sub-paragraph (3)(a), it shall nevertheless close again if, during the period specified in the closure notice in accordance with paragraph 29(8)(a) (or, where the period of twelve months specified in paragraph 29(10) applies, during that period) the number of the contractor's registered patients rises to the number specified in the closure notice in accordance with paragraph 29(8)(d).

(5) Except in cases where the contractor's list of patients is already open pursuant to sub-paragraph (3), the Health Board shall notify the contractor in writing between 7 and 14 days before the expiry of the period of closure specified in sub-paragraph (2), confirming the date on which the contractor's list of patients will re-open.

(6) Where the details specified in the closure notice in accordance with paragraph 29(8) have been revised following discussions under paragraph 29(10), references in this paragraph to details specified in the closure notice are references to those details as so revised.

Rejection of closure notice by the Health Board

31.—(1) This regulation applies where the Health Board rejects the closure notice in accordance with paragraph 29(12)(b).

(2) The contractor and the Health Board may not refer the matter for determination in accordance with the NHS dispute resolution procedure (or, where applicable, commence court proceedings) until the assessment panel has given its determination in accordance with the following sub-paragraphs.

(3) The Health Board must ensure that an assessment panel is appointed by another Health Board as soon as is practicable to consider and determine whether the contractor should be permitted to close its list of patients, and if so, the terms on which the contractor should be permitted to do so.

(4) The Health Board shall provide the assessment panel with such information as the assessment panel may reasonably require to enable the panel to reach a determination and shall include in such information any written observations received from the contractor.

(5) At least one member of the assessment panel shall visit the contractor before reaching a determination under sub-paragraph (6).

(6) Within the period of 28 days beginning with the date on which the Health Board rejected the closure notice, the assessment panel shall—

- (a) approve the list closure; or
- (b) reject the list closure,

and shall notify the Health Board and the contractor of its determination in writing as soon as possible.

(7) Where the assessment panel determines in accordance with sub-paragraph (6)(a) that the contractor's list of patients should close, it shall specify—

- (a) a date from which the closure shall take effect, which must be within a period of 7 days beginning with the date of the assessment panel's determination; and
- (b) those details specified in paragraph 29(8).

(8) Where the assessment panel rejects the list closure in accordance with sub-paragraph (6)(b), that list shall remain open, and the Health Board and the contractor shall enter into discussions with a view to ensuring that the contractor receives support from the Health Board which will enable the contractor to continue to provide services safely and effectively.

(9) Where the assessment panel rejects the list closure in accordance with sub-paragraph (6)(b), the contractor may not submit a further closure notice as described in paragraph 29 until—

- (a) the expiry of a period of three months beginning with the date of the assessment panel's determination; or
- (b) (if applicable) the final determination of the NHS dispute resolution procedure (or any court proceedings),

whichever is the later unless there has been a change in the circumstances of the contractor which affects its ability to deliver services under the contract.

(10) Any decision or determination by the assessment panel for the purposes of this paragraph may be reached by a majority.

Assignment of patients to lists: open lists

32.—(1) A Health Board may, subject to paragraph 34, assign a new patient to a contractor whose list of patients is open.

(2) In this paragraph and in paragraphs 33 and 35 to 37, a “new” patient means a person who—

- (a) is resident (whether or not temporarily) within the area of the Health Board;

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- (b) has been refused inclusion in a list of patients of, or has not been accepted as a temporary resident by, a contractor whose premises are within such an area; and
- (c) wishes to be included in the list of patients of a contractor whose practice premises are within that area.

Assignment of patients to lists: closed lists

33.—(1) A Health Board may not assign a new patient to a contractor which has closed its list of patients except in the circumstances specified in sub-paragraph (2).

(2) A Health Board may, subject to paragraph 34, assign a new patient to a contractor whose practice premises are within the Health Board's area and which has closed its list of patients, if—

- (a) most or all of the providers of essential services (or their equivalent) whose practice premises are within the Health Board's area have closed their lists of patients;
- (b) the assessment panel has determined under paragraph 35(7) that patients may be assigned to the contractor in question, and that determination has not been overturned either by a determination of the Scottish Ministers or the adjudicator under the NHS dispute resolution procedure as modified by paragraph 36(3) or (where applicable) by a court; and
- (c) the Health Board has entered into discussions with the contractor in question regarding the assignment of a patient if such discussions are required under paragraph 37.

Factors relevant to assignments

34. In making an assignment to a contractor under paragraph 32 or 33, the Health Board shall have regard to—

- (a) the wishes and circumstances of the patient to be assigned;
- (b) the distance between the patient's place of residence and the contractor's practice premises;
- (c) whether, during the six months ending on the date on which the application for assignment is received by the Health Board, the patient's name has been removed from the list of patients of any contractor in the area of the Health Board under paragraph 20 or its equivalent provision in relation to a section 17C provider in the area of the Health Board;
- (d) whether the patient's name has been removed from the list of patients of any contractor in the area of the Health Board under paragraph 21 or its equivalent provision in relation to a section 17C provider in the area of the Health Board and, if so, whether the contractor has appropriate facilities to deal with such a patient;
- (e) such other matters as the Health Board considers to be relevant.

Assignments to closed lists: determinations of the assessment panel

35.—(1) This paragraph applies where most or all of the providers of essential services (or their equivalent) whose practice premises are within the area of a Health Board have closed their lists of patients.

(2) If the Health Board wishes to assign new patients to contractors which have closed their lists of patients, it must prepare a proposal to be considered by the assessment panel, and the proposal must include details of those contractors to which the Health Board wishes to assign patients.

(3) The Health Board must ensure that an assessment panel is appointed by another Health Board to consider and determine its proposal made under sub-paragraph (2).

(4) The Health Board shall notify in writing—

- (a) contractors or section 17C providers whose practice premises are within the Health Board's area which—

- (i) have closed their list of patients, and
 - (ii) may, in the opinion of the Health Board, be affected by the determination of the assessment panel; and
- (b) the area medical committee (if any) for the area of the Health Board, that it has referred the matter to the assessment panel.
- (5) In reaching its determination, the assessment panel shall have regard to relevant factors including—
- (a) whether the Health Board has attempted to secure the provision of essential services (or their equivalent) for new patients other than by means of their assignment to contractors with closed lists of patients; and
 - (b) the workload of those contractors likely to be affected by any decision to assign such patients to their list of patients.
- (6) The assessment panel shall reach a determination within the period of 28 days beginning with the date on which the panel was appointed.
- (7) The assessment panel shall determine whether the Health Board may assign patients to contractors which have closed their lists of patients; and if it determines that the Health Board may make such assignments, it shall also determine those contractors to which patients may be assigned.
- (8) The assessment panel may determine that the Health Board may assign patients to contractors other than those contractors specified by the Health Board in its proposal under sub-paragraph (2), as long as the contractors were notified under sub-paragraph(4)(a).
- (9) The assessment panel’s determination shall include its comments on the matters specified in sub-paragraph (5), and shall be notified in writing to those contractors which were notified under sub-paragraph (4)(a).
- (10) Any decision or determination by the assessment panel for the purposes of this paragraph may be reached by a majority.

Assignments to closed lists: NHS dispute resolution procedure relating to determinations of the assessment panel

36.—(1) Where an assessment panel makes a determination under paragraph 35(7) that the Health Board may assign new patients to contractors which have closed their lists of patients, any contractor specified in that determination may refer the matter to the Scottish Ministers to review the determination of the assessment panel.

(2) Where more than one contractor specified in the determination in accordance with paragraph 35(7) wishes to refer the matter for dispute resolution, those contractors may, if they all agree, refer the matter jointly, and in that case the Scottish Ministers shall review the matter in relation to those contractors together.

(3) Where a matter is referred to the Scottish Ministers under sub-paragraph (1) or (2), it shall be determined in accordance with the NHS dispute resolution procedure as modified as follows—

(a) in paragraph 91(3), for “a dispute as mentioned in sub-paragraph (1)” substitute “the matter as mentioned in paragraph 36(1)”;

(b) for paragraph 91(4) substitute—

“(4) The contractor (or contractors) wishing to refer the matter as mentioned in paragraph 36(1) must send the request to the Scottish Ministers within the period of 7 days beginning with the date of the determination by the assessment panel in accordance with paragraph 35(7).”;

(c) for paragraph 91(13) substitute—

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“(13) In this paragraph, “specified period” means such period as the Scottish Ministers shall specify in the request sent under sub-paragraphs (6) or (8), being not less than one, nor more than two, weeks beginning with the date on which the request is given, but the adjudicator may, if the period for determination of the dispute has been extended in accordance with sub-paragraph (19), extend any such period (even after it has expired) and, where it the adjudicator does so, a reference in this paragraph to the specified period is to the period as so extended.”

(d) after paragraph 91(15), there shall be inserted the following sub-paragraphs—

“(16) Subject to sub-paragraph (19), within the period of 21 days beginning with the date on which the matter was referred to the Scottish Ministers, the adjudicator shall determine whether the Health Board may assign patients to contractors which have closed their lists of patients; and if the adjudicator determines that the Health Board may make such assignments, the adjudicator shall also determine those contractors to which patients may be assigned.

(17) The adjudicator may not determine that patients may be assigned to a contractor which was not specified in the determination of the assessment panel under paragraph 35(7).

(18) In the case of a matter referred jointly by contractors in accordance with paragraph 36(2), the adjudicator may determine that patients may be assigned to one, some or all of the contractors which referred the matter.

(19) The period of 21 days referred to in sub-paragraph (15) may be extended (even after it has expired) by a further specified number of days if an agreement to that effect is reached by—

- (a) the adjudicator;
 - (b) the Health Board; and
 - (c) the contractor (or contractors) which referred the matter to dispute resolution.”;
- and

(e) paragraph 92(2) shall not apply.

Assignments to closed lists: assignments of patients by a Health Board

37.—(1) Before the Health Board may assign a new patient to a contractor, it shall, subject to sub-paragraph (3), enter into discussions with that contractor regarding additional support that the Health Board can offer the contractor, and the Health Board shall use its best endeavours to provide appropriate support.

(2) In the discussions referred to in sub-paragraph (1), both parties shall use reasonable endeavours to reach agreement.

(3) The requirement in sub-paragraph (1) to enter into discussions applies—

- (a) to the first assignment of a patient to a particular contractor; and
- (b) to any subsequent assignment to that contractor to the extent that it is reasonable and appropriate having regard to the numbers of patients who have been or may be assigned to it and the period of time since the last discussions under sub-paragraph (1) took place.

PART 3

Prescribing and Dispensing

Prescribing

38. The contractor shall ensure that any prescription form for drugs, medicines or appliances issued by a prescriber complies as appropriate with the requirements in paragraphs 39 to 41.

Prescribing

39.—(1) Subject to paragraphs 40 and 41 a prescriber shall order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the contract by issuing to that patient a prescription form and such a prescription form shall not be used in any other circumstances.

(2) In issuing any such prescription form, the prescriber shall sign the prescription form in ink with the prescriber's initials, or forenames, and surname in the prescriber's own handwriting and not by means of a stamp and shall so sign only after particulars of the order have been inserted in the prescription form, and:

- (a) the prescription form shall not refer to any previous prescription form ; and
- (b) a separate prescription form shall be used for each patient.

(3) In a case of urgency a prescriber may request a pharmacist to dispense a drug or medicine before a prescription form is issued, only if:

- (a) that drug or medicine is not a Scheduled drug;
- (b) that drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971(27) other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001(28); and
- (c) the prescriber undertakes to furnish the pharmacist, within 72 hours, with a prescription form completed in accordance with sub-paragraph (2).

(4) In a case of urgency a prescriber may request a pharmacist to dispense an appliance before a prescription form is issued only if—

- (a) that appliance does not contain a Scheduled drug or a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001;
- (b) in the case of a restricted availability appliance, the patient is a person, or it is for a purpose, specified in the Drug Tariff; and
- (c) the prescriber undertakes to furnish the pharmacist, within 72 hours, with a prescription form completed in accordance with sub-paragraph (2).

Restrictions on prescribing by medical practitioners

40.—(1) In the course of treating a patient to whom a medical practitioner is providing treatment under the contract, the medical practitioner shall not order on a prescription form a drug, medicine or other substance specified in any directions given by the Scottish Ministers under section 17N(6) of the Act (Other mandatory contract terms)(29) as being drugs, medicines or other substances which may not be ordered for patients in the provision of medical services under the contract but may,

(27) 1971 c. 38.

(28) Schedule 4 was amended by S.I. 2003/1432.

(29) Section 17N was inserted by the 2004 Act, section 4.

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subject to regulation 24(2)(b), prescribe such a drug or other substance for that patient in the course of that treatment under a private arrangement.

(2) In the course of treating a patient to whom a medical practitioner is providing treatment under the contract, the medical practitioner shall not order on a prescription form a drug, medicine or other substance specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless—

- (a) that patient is a person of the specified description;
- (b) that drug, medicine or other substance is prescribed for that patient only for the specified purpose; and
- (c) the practitioner endorses the form with the reference “SLS”,

but may, subject to regulation 24(2)(b), prescribe such a drug, medicine or other substance for that patient in the course of that treatment under a private arrangement.

(3) In the course of treating a patient to whom a medical practitioner is providing treatment under the contract, the medical practitioner shall not order on a prescription form a restricted availability appliance unless—

- (a) the patient is a person, or it is for a purpose, specified in the Drug Tariff; and
- (b) the practitioner endorses the face of the form with the reference “SLS”,

but may, subject to regulation 24(2)(b), prescribe such an appliance for that patient in the course of that treatment under a private arrangement.

Restrictions on prescribing by supplementary prescribers

41.—(1) The contractor shall have arrangements in place to secure that a supplementary prescriber will—

- (a) give a prescription for a prescription only medicine;
- (b) administer a prescription only medicine for parenteral administration; or
- (c) give directions for the administration of a prescription only medicine for parenteral administration,

as a supplementary prescriber under the conditions set out in sub-paragraph (2).

(2) The conditions referred to in sub-paragraph (1) are that—

- (a) the supplementary prescriber satisfies the applicable conditions set out in article 3B(3) of the POM Order (prescribing and administration by supplementary prescribers)(**30**), unless those conditions do not apply by virtue of any of the exemptions set out in the subsequent provisions of that Order;
- (b) the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971;
- (c) the drug, medicine or other substance is not specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;
- (d) the drug, medicine or other substance is not specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless—
 - (i) the patient is a person of the specified description,

(30) Article 3B was inserted into the POM Order by S.I. [2003/696](#).

- (ii) the medicine is prescribed for that patient only for the specified purposes, and
- (iii) if the supplementary prescriber is giving a prescription, the supplementary prescriber endorses the face of the form with the reference “SLS”.

(3) Where the functions of a supplementary prescriber include prescribing, the contractor shall have arrangements in place to secure that that person will only give a prescription for—

- (a) an appliance; or
- (b) a medicine which is not a prescription only medicine,

as a supplementary prescriber under the conditions set out in sub-paragraph (4).

(4) The conditions referred to in sub-paragraph (3) are that—

- (a) the supplementary prescriber acts in accordance with a clinical management plan which is in effect at the time the supplementary prescriber acts and which contains the following particulars—
 - (i) the name of the patient to whom the plan relates,
 - (ii) the illness or conditions which may be treated by the supplementary prescriber,
 - (iii) the date on which the plan is to take effect, and when it is to be reviewed by the medical practitioner or dentist who is a party to the plan,
 - (iv) reference to the class or description of medicines or types of appliances which may be prescribed or administered under the plan,
 - (v) any restrictions or limitations as to the strength or dose of any medicine which may be prescribed or administered under the plan, and any period of administration or use of any medicine or appliance which may be prescribed or administered under the plan,
 - (vi) relevant warnings about known sensitivities of the patient to, or known difficulties of the patient with, particular medicines or appliances,
 - (vii) the arrangements for notification of—
 - (aa) suspected or known adverse reactions to any medicine which may be prescribed or administered under the plan, and suspected or known adverse reactions to any other medicine taken at the same time as any medicine prescribed or administered under the plan,
 - (bb) incidents occurring with the appliance which might lead, might have led or has led to the death or serious deterioration of state of the health of the patient, and
 - (viii) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the medical practitioner or dentist who is a party to the plan;
- (b) the supplementary prescriber has access to the health records of the patient to whom the plan relates which are used by any medical practitioner or dentist who is a party to the plan;
- (c) if it is a prescription for a medicine, the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971;
- (d) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;
- (e) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the Scottish Ministers under

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section 17N(6) of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless—

- (i) the patient is a person of the specified description,
 - (ii) the medicine is prescribed for that patient only for the specified purposes, and
 - (iii) when giving the prescription, the supplementary prescriber endorses the face of the form with the reference “SLS”;
- (f) if it is a prescription for a medicine—
- (i) the medicine is the subject of a product licence, a marketing authorisation or a homeopathic certificate of registration granted by the licensing authority or the European Commission, or
 - (ii) subject to paragraph (6), the use of the medicine is for the purposes of a clinical trial, and
 - (aa) that trial is the subject of a clinical trial certificate issued in accordance with the Medicines Act 1968⁽³¹⁾, or
 - (bb) a clinical trial certificate is not needed in respect of that trial by virtue of any exemption conferred by or under that Act;
- (g) if it a prescription for an appliance, the appliance is listed in Parts 2 to 6 or 8 to 10 of the Drug Tariff; and
- (h) if it is a prescription for a restricted availability appliance-
- (i) the patient is a person of a description mentioned in the entry in Part 3 of the Drug Tariff in respect of that appliance,
 - (ii) the appliance is prescribed only for the purposes specified in respect of that person in that entry, and
 - (iii) when giving the prescription, the supplementary prescriber endorses the face of the form with the reference “SLS”.
- (5) In sub-paragraph (4)(a), “clinical management plan” means a plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—
- (a) the patient to whom the plan relates;
 - (b) the medical practitioner or dentist who is a party to the plan; and
 - (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan.

(6) In relation to any time from the coming into force of any regulations made by the Secretary of State under section 2(2) of the European Communities Act 1972 (general implementation of treaties)⁽³²⁾ to implement Directive 2001/83/EC on the Community code relating to medicinal products for human use⁽³³⁾, sub-paragraph (4)(f)(ii) shall be read as if it referred to a clinical trial which has been authorised, or is treated as having been authorised by the licensing authority for the purposes of those Regulations.

Interpretation of paragraphs 38 to 41

42. For the purposes of paragraphs 38 to 41, in their application to a contractor whose contract includes the provision of contraceptive services, drugs includes contraceptive substances and appliances includes contraceptive appliances.

⁽³¹⁾ 1968 c. 67.

⁽³²⁾ 1972 c. 68.

⁽³³⁾ O.J. L 311, 28.11.2001, p. 67.

Excessive prescribing

43.—(1) The contractor shall not prescribe drugs, medicines or appliances whose cost or quantity, in relation to any patient, is, by reason of the character of the drug, medicine or appliance in question in excess of that which was reasonably necessary for the proper treatment of that patient.

(2) In considering whether a contractor has breached its obligations under sub-paragraph (1), the Health Board shall seek the views of the area medical committee for its area.

Provision of dispensing services

44.—(1) A contractor may secure the provision of dispensing services to its registered patients only if it is authorised or required to do so by the Health Board in accordance with this paragraph.

(2) Where the Health Board, is satisfied, after consultation with the area pharmaceutical committee, that a person, by reason of—

- (a) distance;
- (b) inadequacy of means of communication; or
- (c) other exceptional circumstances,

will have serious difficulty in obtaining from a pharmacist any drugs, medicines or appliances, other than scheduled drugs, required for that person's treatment, the Health Board shall require or authorise the contractor with whom the person is a registered patient to supply such drugs, medicines and appliances to that person until further notice.

(3) Notwithstanding anything contained in sub-paragraph (2)—

- (a) a contractor shall not be required to undertake the supply of drugs, medicines, and appliances under sub-paragraph (2) if the contractor satisfies the Health Board that the contractor is not in the habit of dispensing drugs, medicines, and appliances for the contractor's patients;
- (b) a contractor shall be entitled to receive reasonable notice from the Health Board that the contractor is required to undertake the supply of drugs, medicines and appliances under sub-paragraph (2) or that such supply is to be discontinued.

(4) Subject to sub-paragraph (6), a contractor, who is required by the Health Board to supply drugs, medicines and appliances under sub-paragraph (2) to a patient, in the course of treating that patient under these Regulations—

- (a) shall, subject to sub-paragraph (7), record on a prescription form completed in accordance with paragraph 39, an order for supply of any drugs, medicines or appliances which are needed for the treatment of that patient, but shall not be required to issue that form to that patient;
- (b) shall supply those drugs, medicines or appliances for that patient under sub-paragraph (2) but—
 - (i) shall not supply under sub-paragraph (2) for that patient any Scheduled drug specified as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract, except that, where the contractor has ordered a drug which has an appropriate non-proprietary name either by that name or by its formula, the contractor may supply a drug which has the same specification notwithstanding that it is such a Scheduled drug (but, in the case of a drug which combines more than one drug, only if the combination has an appropriate non-proprietary name);
 - (ii) shall supply under sub-paragraph (2) for that patient any Scheduled drug specified as being a drug, medicine or other substance which may only be ordered for specific patients and purposes only where—

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- (aa) that patient is a person of the specified description; and
- (bb) that drug, medicine or other substance is supplied to that patient only for the specified purpose;

(iii) shall supply under sub-paragraph (2) for that patient a restricted availability appliance only if it is for a patient in a category of person or a purpose specified in the Drug Tariff;

- (c) may supply for that patient with the contractor's consent, in respect of that treatment but otherwise than under sub-paragraph (2), any Scheduled drug.

(5) A contractor shall comply with any arrangements made by the Scottish Ministers, or made by the Health Board after consultation with the area medical committee (if any) and the area pharmaceutical committee and approved by the Scottish Ministers, under which the contractor may obtain and have available any drugs, medicines or appliances which the contractor is required or entitled to supply in terms of this paragraph.

(6) Sub-paragraph (4) does not apply to drugs, medicines or appliances ordered on a prescription form by a supplementary prescriber or an independent nurse prescriber.

(7) Where a patient presents an order on a prescription form for listed drugs or medicines, or appliances, signed by a supplementary prescriber or an independent nurse prescriber, to a contractor who is required under sub-paragraph (2) to provide drugs or appliances to that patient, the contractor may provide to the patient such drugs, medicines or appliances so ordered as the contractor supplies in the normal course of the contractor's practice.

(8) A drug supplied by a contractor unless administered in person shall be supplied in a suitable container.

(9) Before supplying the drugs, medicines or appliances recorded on a prescription form in accordance with sub-paragraph (4) or providing the drugs or medicines or appliances ordered on a prescription form signed by a supplementary prescriber or an independent nurse prescriber in accordance with sub paragraph (7) a contractor who is required by the Health Board under sub-paragraph (2) to provide drugs, medicines or appliances to a patient shall request any person who makes a declaration on the prescription form claiming either charge exemption under regulation 7 of the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2001⁽³⁴⁾ ("the 2001 Regulations") or charge remission under the National Health Service (Travelling Expenses and Remission of Charges) (Scotland) (No 2) Regulations 2003⁽³⁵⁾ to provide evidence of the patient's entitlement to such exemption or remission.

(10) Sub-paragraph (9) shall not apply in respect of claims for exemption under regulation 7(1)(a) to (f) of the 2001 Regulations where the dispensing contractor has information in the contractor's possession at the time of supplying the item which confirms that the patient is entitled to the exemption claimed.

(11) Where the person presenting the prescription form does not show valid evidence of entitlement and the dispensing contractor, in respect of a claim for exemption made under regulation 7(1)(a) to (f) of the 2001 Regulations does not have evidence in the contractor's possession to confirm that the patient is entitled to make that claim, the dispensing contractor shall mark the patient's prescription form accordingly before supplying the prescribed item.

(12) The provisions of regulation 24 (fees and charges) apply in respect of the provision of any drugs, medicines or appliances by a contractor providing dispensing services as they apply in respect of prescriptions for drugs, medicines or appliances.

(13) Nothing in this paragraph shall prevent a contractor providing a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

⁽³⁴⁾ S.S.I. 2001/430, as amended by S.S.I. 2002/100 and 2003/130 and 295.

⁽³⁵⁾ S.S.I. 2003/460.

Provision of drugs, medicines and appliances for immediate treatment or personal administration

45.—(1) Subject to sub-paragraph (2), a contractor—

- (a) shall provide to a patient any drug, medicine or appliance, not being a Scheduled drug, where such provision is needed for the immediate treatment of that patient before a provision can otherwise be obtained; and
- (b) may provide to a patient any drug, medicine or appliance, not being a Scheduled drug, which the contractor personally administers or applies to that patient,

but shall, in either case, provide a restricted availability appliance only if it is for a person or a purpose specified in the Drug Tariff.

(2) Nothing in sub-paragraph (1) authorises a person to supply any drug or medicine to a patient otherwise than in accordance with Part 3 of the Medicines Act 1968⁽³⁶⁾ or any regulations or orders made thereunder.

PART 4

Persons who perform services

Qualifications of performers

46.—(1) Subject to sub-paragraph (2), no medical practitioner shall perform medical services under the contract unless the practitioner is—

- (a) included in the primary medical services performers' list for the Health Board which is under a duty to provide or secure the provision of the service to be performed;
- (b) not suspended from that list or from the Medical Register; and
- (c) not subject to interim suspension under section 41A of the Medical Act 1983 (interim orders)⁽³⁷⁾.

(2) Sub-paragraph (1) (a) shall not apply in the case of—

- (a) a medical practitioner employed in Scotland, by a Health Board, in England and Wales, by a NHS trust, a NHS foundation trust, or, in Northern Ireland, by a Health and Social Services trust who is providing services other than primary medical services at the practice premises;
- (b) a person who is provisionally registered under section 15 (provisional registration), 15A (provisional registration for EEA nationals) or 21 (provisional registration) of the Medical Act 1983⁽³⁸⁾ acting in the course of the person's employment in a resident medical capacity in an approved medical practice; or
- (c) a GP Registrar during the first two months of the GP Registrar's training period.

Qualifications of performers

47. No health care professional other than one to whom paragraph 46 applies shall perform clinical services under the contract unless the health care professional is appropriately registered

⁽³⁶⁾ 1968 c. 67.

⁽³⁷⁾ 1983 c. 54. Section 41A was inserted by S.I. 2000/1803.

⁽³⁸⁾ Section 15 was amended by the National Health Service (Primary Care) Act 1997 (c. 46) ("the 1997 Act"), Schedule 1, Part 1, paragraph 61(9); section 15A was inserted by S.I. 2000/3041; section 21 was amended by the 1997 Act, Schedule 1, Part 1, paragraph 61(5) and by S.I. 1996/1591 and 2002/3135.

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with the health care professional's relevant professional body and the health care professional's registration is not currently suspended.

Qualifications of performers

48. Where the registration of a health care professional or, in the case of a medical practitioner, the practitioner's inclusion in a list, is subject to conditions, the contractor shall ensure compliance with those conditions insofar as they are relevant to the contract.

Qualifications of performers

49. No health care professional shall perform any clinical services unless the health care professional has such clinical experience and training as are necessary to enable the health care professional properly to perform such services.

Conditions for employment and engagement

50.—(1) Subject to sub-paragraphs (2) and (3), a contractor shall not employ or engage a medical practitioner (other than one falling within paragraph 46(2)) unless—

- (a) that practitioner has provided it with the name and address of the Health Board on whose primary medical services performers list the practitioner appears;
- (b) the contractor has checked that the practitioner meets the requirements in paragraph 46.

(2) Where the employment or engagement of a medical practitioner is urgently needed and it is not possible for the contractor to check the matters referred to in paragraph 46 in accordance with sub-paragraph (1)(b) before employing or engaging the practitioner, the practitioner may be employed or engaged on a temporary basis for a single period of up to 7 days whilst such checks are undertaken.

(3) Where the prospective employee is a GP Registrar, the requirements set out in sub-paragraph (1) shall apply with the modifications that—

- (a) the name and address provided under sub-paragraph (1) may be the name and address of the Health Board on whose primary medical services performers list the GP Registrar has applied for inclusion; and
- (b) confirmation that the GP Registrar's name appears on that list shall not be required until the end of the first two months of the GP Registrar's training period.

Conditions for employment and engagement

51.—(1) A contractor shall not employ or engage—

- (a) a health care professional (other than one to whom paragraph 46 applies) unless the contractor has checked that the health care professional meets the requirements in paragraph 47; or
- (b) a health care professional to perform clinical services unless the contractor has taken reasonable steps to satisfy itself that the health care professional meets the requirements in paragraph 49.

(2) Where the employment or engagement of a health care professional is urgently needed and it is not possible to check the matters referred to in paragraph 47 in accordance with sub-paragraph (1) before employing or engaging the practitioner, the health care professional may be employed or engaged on a temporary basis for a single period of up to 7 days whilst such checks are undertaken.

(3) When considering a health care professional's experience and training for the purposes of sub-paragraph (1)(b), the contractor shall have regard in particular to—

- (a) any post-graduate or post-registration qualification held by the health care professional; and
- (b) any relevant training undertaken by the health care professional and any relevant clinical experience gained by the health care professional.

Conditions for employment and engagement

52.—(1) The contractor shall not employ or engage a health care professional to perform medical services under the contract unless—

- (a) that person has provided two clinical references, relating to two recent posts (which may include any current post) as a health care professional which lasted for three months without a significant break, or where this is not possible, a full explanation and alternative referees; and
- (b) the contractor has checked and is satisfied with the references.

(2) Where the employment or engagement of a medical practitioner is urgently needed and it is not possible to obtain and check the references in accordance with sub-paragraph (1)(b) before employing or engaging the practitioner, the practitioner may be employed or engaged on a temporary basis for a single period of up to 14 days whilst the practitioner's references are checked and considered, and for an additional single period of a further 7 days if the contractor believes the person supplying those references is ill, on holiday or otherwise temporarily unavailable.

(3) Where the contractor employs or engages the same person on more than one occasion within a period of three months, it may rely on the references provided on the first occasion, provided that those references are not more than twelve months old.

Conditions for employment and engagement

53.—(1) Before employing or engaging any person to assist it in the provision of services under the contract, the contractor shall take reasonable care to satisfy itself that the person in question is both suitably qualified and competent to discharge the duties for which the person is to be employed or engaged.

(2) The duty imposed by sub-paragraph (1) is in addition to the duties imposed by paragraphs 50 to 52.

(3) When considering the competence and suitability of any person for the purpose of sub-paragraph (1), the contractor shall have regard, in particular, to—

- (a) that person's academic and vocational qualifications;
- (b) that person's education and training; and
- (c) that person's previous employment or work experience.

Training

54. The contractor shall ensure that for any health care professional who is—

- (a) performing clinical services under the contract; or
- (b) employed or engaged to assist in the performance of such services,

there are in place arrangements for the purpose of maintaining and updating the health care professional's skills and knowledge in relation to the services which the health care professional is performing or assisting in performing.

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Training

55. The contractor shall afford to each employee reasonable opportunities to undertake appropriate training with a view to maintaining that employee's competence.

Terms and conditions

56. The contractor shall only offer employment to a general medical practitioner on terms and conditions which are no less favourable than those contained in the "Model terms and conditions of service for a salaried general practitioner employed by a GMS practice" published by the British Medical Association and the NHS Confederation as item 1.2 of the supplementary documents to the new GMS contract 2003⁽³⁹⁾.

Arrangements for GP Registrars

57.—(1) The contractor shall only employ a GP Registrar for the purpose of being trained by a GP Trainer with the agreement of the Scottish Ministers and subject to the conditions in sub-paragraph (2).

(2) The conditions referred to in sub-paragraph (1) are that the contractor shall not, by reason only of having employed or engaged a GP Registrar, reduce the total number of hours for which other medical practitioners perform primary medical services under the contract or for which other staff assist them in the performance of those services.

(3) A contractor which employs a GP Registrar shall—

- (a) offer the GP Registrar terms of employment in accordance with the rates and subject to the conditions contained in any directions given by the Scottish Ministers to Health Boards under section 17M of the Act⁽⁴⁰⁾ concerning the grants, fees, travelling and other allowances payable to GP Registrars; and
- (b) take into account any guidance issued by the Scottish Ministers in relation to the GP Registrar Scheme⁽⁴¹⁾.

Independent nurse prescribers and supplementary prescribers

58.—(1) Where—

- (a) a contractor employs or engages a person who is an independent nurse prescriber or a supplementary prescriber whose functions will include prescribing;
- (b) a contractor is a partnership and one of the partners is an independent nurse prescriber or a supplementary prescriber whose functions will include prescribing; or
- (c) the functions of a person who is an independent nurse prescriber or a supplementary prescriber whom the contractor already employs or has already engaged are extended to include prescribing,

it shall notify the Health Board in writing within the period of 7 days beginning with the date on which the contractor employed or engaged the person, the party became a party to the contract (unless, immediately before becoming such a party, the person fell under paragraph (1)(a)) or the person's functions were extended, as the case may be.

⁽³⁹⁾ This document is published jointly by the General Practitioners Committee of the British Medical Association and the NHS Confederation. It is available on the Department of Health's website at www.doh.gov.uk/gmscontract/supportingdoc.htm or a copy may be obtained by writing to the NHS Confederation, 1 Warwick Road, London SW1E 5ER.

⁽⁴⁰⁾ Section 17M was inserted by the 2004 Act, section 4.

⁽⁴¹⁾ The current guidance is the GP Registrar Scheme Vocational Guide for General Medical practice—the UK Guide 2000 published by the Department of Health and available on their website at www.doh.gov.uk/medicaltrainingintheuk or by writing to the Department of Health, P.O. Box 777, London SE1 6XH.

(2) Where—

- (a) the contractor ceases to employ or engage a person who is an independent nurse prescriber or a supplementary prescriber whose functions included prescribing in its practice;
- (b) the partner in a partnership who is an independent nurse prescriber or a supplementary prescriber whose functions include prescribing, ceases to be partner in a partnership;
- (c) the functions of a person who is an independent nurse prescriber or a supplementary prescriber whom the contractor employs or engages in its practice are changed so that they no longer include prescribing in its practice; or
- (d) the contractor becomes aware that a person who is an independent nurse prescriber or a supplementary prescriber whom the contractor employs or engages has been removed or suspended from the relevant register,

it shall notify the Health Board in writing by the end of the second working day after the day when the event occurred.

(3) The contractor shall provide the following information when it notifies the Health Board in accordance with sub-paragraph (1)—

- (a) the person's full name;
- (b) the person's professional qualifications;
- (c) the person's identifying number which appears in the relevant register;
- (d) the date on which the person's entry in the relevant register was annotated to the effect that the person was qualified to order drugs, medicines and appliances for patients;
- (e) the date—
 - (i) on which the person was employed or engaged, if applicable,
 - (ii) the person became a partner in the partnership, if applicable, or
 - (iii) on which one of the person's functions became prescribing in its practice.

(4) The contractor shall provide the following information when it notifies the Health Board in accordance with sub-paragraph (2)—

- (a) the person's full name;
- (b) the person's professional qualifications;
- (c) the person's identifying number which appears in the relevant register;
- (d) the date—
 - (i) the person ceased to be employed or engaged in its practice,
 - (ii) the person ceased to be partner in the partnership,
 - (iii) the person's functions changed so as no longer to include prescribing, or
 - (iv) on which the person was removed or suspended from the relevant register.

Signing of documents

59.—(1) In addition to any other requirements relating to such documents whether in these Regulations or otherwise, the contractor shall ensure that the documents specified in sub-paragraph (2) include—

- (a) the clinical profession of the health care professional who signed the document; and
- (b) the name of the contractor on whose behalf it is signed.

(2) The documents referred to in sub-paragraph (1) are—

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- (a) certificates issued in accordance with regulation 21, unless regulations relating to particular certificates provide otherwise;
- (b) prescription forms; and
- (c) any other clinical documents.

Level of skill

60. The contractor shall carry out its obligations under the contract with reasonable skill and care.

Appraisal and assessment

61.—(1) The contractor shall ensure that any medical practitioner performing services under the contract—

- (a) participates in the appraisal system provided by the Health Board unless the practitioner participates in an appropriate appraisal system provided by another health service body or is an armed forces GP; and
- (b) co-operates with any assessment process which the Health Board operates in relation to poorly performing doctors, as set out in NHS circular PCA(M)(2001)17(42).

(2) The Health Board shall provide an appraisal system for the purposes of sub-paragraph (1) (a) after consultation with the area medical committee and such other persons as appear to it to be appropriate.

(3) In sub-paragraph (1)—

“armed forces GP” means a medical practitioner who is employed on a contract of service by the Ministry of Defence, whether or not as a member of the United Kingdom Armed Forces of Her Majesty; and

“health service body” does not include any person who is to be regarded as a health service body in accordance with regulation 10.

Sub-contracting of clinical matters

62.—(1) Subject to sub-paragraph (2), the contractor shall not sub-contract any of its rights or duties under the contract in relation to clinical matters unless—

- (a) in all cases, including those which fall within paragraph 63, it has taken reasonable steps to satisfy itself that—
 - (i) it is reasonable in all the circumstances; and
 - (ii) that person is qualified and competent to provide the service; and
- (b) except in cases which fall within paragraph 63, it has notified the Health Board of its intention to sub-contract as soon as reasonably practicable before the date on which the proposed sub-contract is intended to come into force.

(2) Sub-paragraph (1)(b) shall not apply to a contract for services with a health care professional for the provision by that person of clinical services.

(3) The notification referred to in sub-paragraph (1)(b) shall include-

- (a) the name and address of the proposed sub-contractor;
- (b) the duration of the proposed sub-contract;
- (c) the services to be covered; and

(42) Copies of NHS Circular PCA(M) (2001)17 may be obtained in writing from the Scottish Executive Health Department, Primary Care Division, St Andrew’s House, Regent Road, Edinburgh, EH1 3DG.

(d) the address of any premises to be used for the provision of services.

(4) Following receipt of a notice in accordance with sub-paragraph (1)(b), the Health Board may request such further information relating to the proposed sub-contract as appears to it to be reasonable and the contractor shall supply such information promptly.

(5) The contractor shall not proceed with the sub-contract or, if it has already taken effect, shall take appropriate steps to terminate it, where, within 28 days of receipt of the notice referred to in sub-paragraph (1)(b), the Health Board has served notice of objection to the sub-contract on the grounds that—

(a) the sub-contract would—

- (i) put at serious risk the safety of the contractor's patients, or
- (ii) put the Board at risk of material financial loss; or

(b) the sub-contractor would be unable to meet the contractor's obligations under the contract.

(6) Where the Health Board objects to a proposed sub-contract in accordance with sub-paragraph (5), it shall include with the notice of objection a statement in writing of the reasons for its objections.

(7) Sub-paragraphs (1) and (3) to (6) shall also apply in relation to any renewal or material variation of a sub-contract in relation to clinical matters.

(8) Where a Health Board does not object to a proposed sub-contract under paragraph (5), the parties to the contract shall be deemed to have agreed a variation of the contract which has the effect of adding to the list of practice premises any premises whose address was notified to it under sub-paragraph (3)(d) and paragraph 94 (1) shall not apply.

(9) A contract with a sub-contractor must prohibit the sub-contractor from sub-contracting the clinical services it has agreed with the contractor to provide.

Sub-contracting of out of hours service

63.—(1) A contractor shall not, otherwise than in accordance with the written approval of the Health Board, sub-contract all or part of its duty to provide out of hours services to any person other than those listed in sub-paragraph (2) other than on a short-term occasional basis.

(2) The persons referred to in sub-paragraph (1) are—

- (a) a person who holds a general medical services contract with a Health Board which includes out of hours services;
- (b) a section 17C provider who is required to provide the equivalent of essential services to the provider's patients during all or part of the out of hours period;
- (c) a health care professional, not falling within paragraph (a) or (b), who is to provide the out of hours services personally under a contract for services; or
- (d) a group of medical practitioners, whether in partnership or not, who provide out of hours services for each other under informal rota arrangements.

(3) An application for approval under sub-paragraph (1) shall be made by the contractor in writing to the Health Board and shall state—

- (a) the name and address of the proposed sub-contractor;
- (b) the address of any premises used for the provision of services;
- (c) the duration of the proposed sub-contract;
- (d) the services to be covered by the arrangement; and
- (e) how it is proposed that the sub-contractor will meet the contractor's obligations under the contract in respect of the services covered by the arrangement.

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(4) Within 7 days of receipt of an application under sub-paragraph (3), a Health Board may request such further information relating to the proposed arrangements as seem to it to be reasonable.

(5) Within 28 days of receipt of an application which meets the requirements specified in sub-paragraph (3) or the further information requested under sub-paragraph (4) (whichever is the later), the Health Board shall—

- (a) approve the application;
- (b) approve the application with conditions; or
- (c) refuse the application.

(6) The Health Board shall not refuse the application if it is satisfied that the proposed arrangement will, in respect of the services to be covered, enable the contractor to meet satisfactorily its obligations under the contract and will not—

- (a) put at serious risk the safety of the contractor's patients; or
- (b) put the Health Board at risk of material financial loss.

(7) The Health Board shall inform the contractor by notice in writing of its decision on the application and, where it refuses an application, it shall include in the notice a statement of the reasons for its refusal.

(8) Where a Health Board approves a sub-contract under this paragraph the parties to the contract shall be deemed to have agreed a variation of the contract which has the effect of adding to the list of practice premises for the purposes of the provision of services in accordance with that application, any premises whose address was notified to it under sub-paragraph (3)(b) and paragraph 94 (1) shall not apply.

(9) Sub-paragraphs (1) to (8) shall also apply in relation to any renewal or material variation of a sub-contract in relation to out of hours services.

(10) A contract with a sub-contractor must prohibit the sub-contractor from sub-contracting the out of hours services it has agreed with the contractor to provide.

Withdrawal and variation of approval under paragraph 63

64.—(1) Without prejudice to any other remedies which it may have under the contract, where a Health Board has approved an application made under paragraph 63(3) it shall, subject to paragraph 65, be entitled to serve notice on the contractor withdrawing or varying that approval from a date specified in the notice if it is no longer satisfied that the proposed arrangement will enable the contractor to meet satisfactorily its obligations under the contract.

(2) The date specified in the notice shall be such as appears reasonable in all the circumstances to the Health Board.

(3) The notice referred to in sub-paragraph (1) shall take effect on whichever is the later of—

- (a) the date specified in the notice; or
- (b) (if applicable) the date of the final determination of the NHS dispute resolution procedure (or any court proceedings) relating to the notice in favour of the Health Board.

Withdrawal and variation of approval under paragraph 63

65.—(1) Without prejudice to any other remedies which it may have under the contract, where a Health Board has approved an application made under paragraph 63(3) it shall be entitled to serve notice on the contractor withdrawing or varying that approval with immediate effect if—

- (a) it is no longer satisfied that the proposed arrangement will enable the contractor to meet satisfactorily its obligations under the contract; and

- (b) it is satisfied that immediate withdrawal or variation is necessary to protect the safety of the contractor's patients.
- (2) An immediate withdrawal of approval under sub-paragraph (1) shall take effect on the date on which the notice referred to in that sub-paragraph is received by the contractor.

PART 5

Records, Information, Notifications and Rights of Entry

Patient records

66.—(1) In this paragraph, “computerised records” means records created by way of entries on a computer.

(2) The contractor shall keep adequate records of its attendance on and treatment of its patients and shall do so—

- (a) on forms supplied to it for the purpose by the Health Board; or
- (b) with the written consent of the Health Board, by way of computerised records, or in a combination of those two ways.

(3) The contractor shall include in the records referred to in sub-paragraph (2) clinical reports sent in accordance with paragraph 7 of this Schedule or from any other health care professional who has provided clinical services to a person on its list of patients.

(4) The consent of the Health Board required by sub-paragraph (2)(b) shall not be withheld or withdrawn provided the Health Board is satisfied, and continues to be satisfied, that—

- (a) the computer system upon which the contractor proposes to keep the records has been accredited by the Scottish Ministers or another person on their behalf as suitable for that purpose in accordance with “RFA V.1.—Requirements for Accreditation in General Practice Computer Systems in Scotland”(43);
- (b) the security measures, audit and system management functions incorporated into the computer system as accredited in accordance with paragraph (a) have been enabled; and
- (c) the contractor is aware of, and has signed an undertaking that it will have regard to any guidelines issued by the Scottish Ministers and notified, in writing, to the contractor by the Health Board concerning good practice in the keeping of electronic patient records.

(5) Where a patient's records are computerised records, the contractor shall, as soon as possible following a request from the Health Board, allow the Board to access the information recorded on the contractor's computer system by means of the audit function referred to in sub-paragraph (4)(b) to the extent necessary for the Board to confirm that the audit function is enabled and functioning correctly.

(6) The contractor shall send the complete records relating to a patient to the Health Board—

- (a) where a person on its list dies, before the end of the period of 14 days beginning with the date on which it was informed by the Health Board of the death, or (in any other case) before the end of the period of one month beginning with the date on which it learned of the death; or
- (b) in any other case where the person is no longer registered with the contractor, as soon as possible, at the request of the Health Board.

(43) RFA V.1 is published on Scottish Health On the Web (SHOW) at the following link:<http://www.show.scot.nhs.uk/publications/me/gpcomputerrecords/rfav1.pdf>.

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(7) To the extent that a patient's records are computerised records, the contractor complies with sub-paragraph (6) if it sends to the Health Board a copy of those records—

- (a) in written form; or
- (b) with the written consent of the Health Board, in any other form.

(8) The consent of the Health Board to the transmission of information other than in written form for the purposes of sub-paragraph (7)(b) shall not be withheld or withdrawn provided it is satisfied, and continues to be satisfied, with the following matters—

- (a) the contractor's proposals as to how the record will be transmitted;
- (b) the contractor's proposals as to the format of the transmitted record;
- (c) how the contractor will ensure that the record received by the Health Board is identical to that transmitted; and
- (d) how a written copy of the record can be produced by the Health Board.

(9) A contractor whose patient records are computerised records shall not disable, or attempt to disable, either the security measures or the audit and system management functions referred to in sub-paragraph (4)(b).

Access to records for the purpose of the Quality Information Preparation Scheme

67.—(1) The contractor must provide access to its patient records on request to any appropriately qualified person with whom the Health Board has made arrangements for the provision of the Quality Information Preparation Scheme referred to in section 7 of the GMS Statement of Financial Entitlements.

(2) The contractor shall not be obliged to grant access to a person referred to in sub-paragraph (1) unless that person produces, on request, written evidence that that person is authorised by the Health Board to act on its behalf.

Confidentiality of personal data

68. The contractor shall nominate a person with responsibility for practices and procedures relating to the confidentiality of personal data held by it.

Practice leaflet

69. The contractor shall—

- (a) compile a document (in this paragraph called a practice leaflet) which shall include the information specified in Schedule 8;
- (b) review its practice leaflet at least once in every period of twelve months and make any amendments necessary to maintain its accuracy; and
- (c) make available a copy of the leaflet, and any subsequent updates, to its patients and prospective patients.

Provision of information

70.—(1) Subject to sub-paragraph (2), the contractor shall, at the request of the Health Board, produce to the Board or to a person authorised in writing by the Board or allow it, or a person authorised in writing by it, to access—

- (a) any information which is reasonably required by the Board for the purposes of or in connection with the contract; and

- (b) any other information which is reasonably required in connection with the Health Board's functions.

(2) The contractor shall not be required to comply with any request made in accordance with sub-paragraph (1) unless it has been made by the Health Board in accordance with directions relating to the provision of information by contractors given to it by the Scottish Ministers under section 2(5) of the Act.

Inquiries about prescriptions and referrals

71.—(1) The contractor shall, subject to sub-paragraphs (2) and (3), sufficiently answer any inquiry whether oral or in writing from the Health Board concerning—

- (a) any prescription form issued by a prescriber;
- (b) the considerations by reference to which prescribers issue such forms;
- (c) the referral by or on behalf of the contractor of any patient to any other services provided under the Act; or
- (d) the considerations by which the contractor makes such referrals or provides for them to be made on its behalf.

(2) An inquiry referred to in sub-paragraph (1) may only be made for the purpose either of obtaining information to assist the Health Board to discharge its functions or of assisting the contractor in the discharge of its obligations under the contract.

(3) The contractor shall not be obliged to answer any inquiry referred to in sub-paragraph (1) unless it is made—

- (a) in the case of sub-paragraph (1)(a) or (b), by an appropriately qualified health care professional;
- (b) in the case of sub-paragraph (1)(c) or (d), by an appropriately qualified medical practitioner,

appointed in either case by the Health Board to assist the Board in the exercise of its functions under this paragraph and that person produces, on request, written evidence that the person is authorised by the Health Board to make such an inquiry on its behalf.

Reports to a medical officer

72.—(1) The contractor shall, if it is satisfied that the patient consents—

- (a) supply in writing to a medical officer within such reasonable period as that officer, or an officer of the Department for Work and Pensions on that officer's behalf and at that officer's direction, may specify, such clinical information as the medical officer considers relevant about a patient to whom the contractor or a person acting on its behalf has issued or has refused to issue a medical certificate; and
- (b) answer any inquiries by a medical officer, or by an officer of the Department of Work and Pensions on that officer's behalf and at that officer's direction, about a prescription form or medical certificate issued by the contractor or on its behalf or about any statement which the contractor or a person acting on its behalf has made in a report.

(2) For the purpose of satisfying the contractor that the patient has consented as required by paragraph (1), the contractor may (unless it has reason to believe the patient does not consent) rely on an assurance in writing from the medical officer, or any officer of the Department for Work and Pensions, that that officer holds the patient's written consent.

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Annual return and review

73.—(1) The contractor shall submit an annual return relating to the contract to the Health Board which shall require the same categories of information from all persons who hold contracts with that Board.

(2) Following receipt of the return referred to in sub-paragraph (1), the Health Board shall arrange with the contractor an annual review of its performance in relation to the contract.

(3) Either the contractor or the Health Board may, if it wishes to do so, invite the area medical committee for the area of the Health Board to participate in the annual review.

(4) The Health Board shall prepare a draft record of the review referred to in sub-paragraph (2) for comment by the contractor and, having regard to such comments, shall produce a final written record of the review.

(5) A copy of the final record referred to in sub-paragraph (4) shall be sent to the contractor.

Notifications to the Health Board

74.—(1) In addition to any requirements of notification elsewhere in the regulations, the contractor shall notify the Health Board in writing, as soon as reasonably practicable, of—

- (a) any serious incident that, in the reasonable opinion of the contractor, affects or is likely to affect the contractor's performance of its obligations under the contract;
- (b) any circumstances which give rise to the Health Board's right to terminate the contract under paragraph 101,102 or 103(1);
- (c) any appointments system which it proposes to operate and the proposed discontinuance of any such system; and
- (d) any change of which it is aware in the address of a registered patient; and
- (e) the death of any patient of which it is aware.

Notifications to the Health Board

75. The contractor shall, unless it is impracticable for it to do so, notify the Health Board in writing within 28 days of any occurrence requiring a change in the information about it published by the Health Board in accordance with regulations made under section 2C(3) of the Act (Function of Health Boards: primary medical services)(44).

Notifications to the Health Board

76. The contractor shall notify the Health Board in writing of any person other than a registered patient or a person whom it has accepted as a temporary resident to whom it has provided the essential services described in regulation 15(6) or (8) within the period of 28 days beginning on the day that the services were provided.

Notice provisions specific to a contract with a company limited by shares

77.—(1) A contractor which is a company limited by shares shall give notice in writing to the Health Board forthwith when—

- (a) any share in the contractor is transmitted or transferred (whether legally or beneficially) to another person on a date after the contract has come into force;

(44) Section 2C was inserted by the 2004 Act, section 1(2).

- (b) it passes a resolution or a court of competent jurisdiction makes an order that the contractor be wound up;
 - (c) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the contractor;
 - (d) circumstances arise which would enable the court to make a winding up order in respect of the contractor; or
 - (e) the contractor is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 (definition of inability to pay debts)⁽⁴⁵⁾.
- (2) A notice under sub-paragraph (1)(a) shall confirm that the new shareholder, or, as the case may be, the personal representative of a deceased shareholder—
- (a) is a medical practitioner, or that the new shareholder or, as the case may be, personal representative satisfies the conditions specified in section 17L(2)(c)(i) to (viii) of the Act (eligibility to be contractor under general medical services contract)⁽⁴⁶⁾; and
 - (b) meets the further conditions imposed on shareholders by virtue of regulations 4 and 5.

Notice provisions specific to a contract with persons practising in partnership

78.—(1) A contractor which is a partnership shall give notice in writing to the Health Board forthwith when—

- (a) a partner leaves or informs the other members of the partnership that the partner intends to leave the partnership, and the date upon which the partner left or will leave the partnership;
 - (b) a new partner joins the partnership.
- (2) A notice under sub-paragraph (1)(b) shall—
- (a) state the date that the new partner joined the partnership;
 - (b) confirm that the new partner is a medical practitioner, or that the partner satisfies the conditions specified in 17L(2)(c)(i) to (viii) of the Act;
 - (c) confirm that the new partner meets the conditions imposed by regulations 4 and 5; and
 - (d) state whether the new partner is a general or a limited partner.

Notification of deaths

79.—(1) The contractor shall report, in writing, to the Health Board, the death on its practice premises of any patient no later than the end of the first working day after the date on which the death occurred.

- (2) The report shall include—
- (a) the patient's full name;
 - (b) the patient's National Health Service number where known;
 - (c) the date and place of death;
 - (d) a brief description of the circumstances, as known, surrounding the death;
 - (e) the name of any medical practitioner or other person treating the patient whilst on the practice premises; and
 - (f) the name, where known, of any other person who was present at the time of the death.

⁽⁴⁵⁾ 1986 c. 45.

⁽⁴⁶⁾ Section 17L was inserted by the 2004 Act, section 4.

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(3) The contractor shall send a copy of the report referred to in sub-paragraph (1) to any other Health Board in whose area the deceased was resident at the time of the patient's death.

Notifications to patients following variation of the contract

80. Where the contract is varied in accordance with Part 8 of this Schedule and, as a result of that variation—

- (a) there is to be a change in the range of services provided to the contractor's registered patients; or
- (b) patients who are on the contractor's list of patients are to be removed from that list,

the Health Board shall notify those patients in writing of the variation and its effect and inform them of the steps they can take to obtain elsewhere the services in question or, as the case may be, register elsewhere for the provision of essential services (or their equivalent).

Entry and inspection by the Health Board

81.—(1) Subject to the conditions in sub-paragraph (2), the contractor shall allow persons authorised in writing by the Health Board to enter and inspect the practice premises at any reasonable time.

- (2) The conditions referred to in sub-paragraph (1) are that—
 - (a) reasonable notice of the intended entry has been given;
 - (b) written evidence of the authority of the person seeking entry is produced to the contractor on request; and
 - (c) entry is not made to any premises or part of the premises used as residential accommodation without the consent of the resident.

(3) Either the contractor or the Health Board may, if it wishes to do so, invite the area medical committee for the area of the Board to be present at an inspection of the practice premises which takes place under this paragraph.

PART 6

Complaints

Complaints procedure

82.—(1) The contractor shall establish and operate a complaints procedure to deal with any complaints in relation to any matter reasonably connected with the provision of services under the contract which shall comply with the requirements in paragraphs 83 to 86 and 88.

- (2) The contractor shall take reasonable steps to ensure that patients are aware of—
 - (a) the complaints procedure; and
 - (b) the role of the Health Board and other bodies in relation to complaints about services under the contract.

(3) The contractor shall take reasonable steps to ensure that the complaints procedure is accessible to all patients.

Making of complaints

83. A complaint may be made by or, with the patient's consent, on behalf of a patient, or former patient, who is receiving or has received services under the contract or—

- (a) where a patient is a child—
 - (i) by either parent, or in the absence of both parents, the guardian or other adult who has care of the child,
 - (ii) by a person duly authorised by the local authority, where the child is in the care of that local authority under the Children (Scotland) Act 1995⁽⁴⁷⁾; or
 - (iii) by a person duly authorised by a voluntary organisation by which the child is being accommodated under the provisions of that Act;
- (b) where the patient is incapable of making a complaint, by a relative or other adult who has an interest in the patient's welfare.

Making of complaints

84. Where a patient has died, a complaint may be made by a relative or other adult who had an interest in the patient's welfare or, where the patient falls within paragraph 83(a)(ii) or (iii), by the authority or voluntary organisation.

Period for making complaints

85.—(1) Subject to sub-paragraph (2), the period for making a complaint is—

- (a) six months from the date on which the matter which is the subject of the complaint occurred; or
- (b) six months from the date on which the matter which is the subject of the complaint comes to the complainant's notice provided that the complaint is made no later than twelve months after the date on which the matter which is the subject of the complaint occurred.

(2) Where a complaint is not made during the period specified in sub-paragraph (1), it shall be referred to the person nominated under paragraph 86(2)(a) and if the person is of the opinion that—

- (a) having regard to all the circumstances of the case, it would have been unreasonable for the complainant to make the complaint within that period; and
- (b) notwithstanding the time that has elapsed since the date on which the matter which is the subject matter of the complaint occurred, it is still possible to investigate the complaint properly,

the complaint shall be treated as if it had been received during the period specified in sub-paragraph (1).

Further requirements for complaints procedures

86.—(1) A complaints procedure shall also comply with the requirements set out in sub-paragraphs (2) to (6).

(2) The contractor must nominate—

- (a) a person (who need not be connected with the contractor and who, in the case of an individual, may be specified by the person's job title) to be responsible for the operation of the complaints procedure and the investigation of complaints; and

(47) 1995 c. 36.

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- (b) a partner, or senior person associated with the contractor, to be responsible for the effective management of the complaints procedure and for ensuring that action is taken in the light of the outcome of any investigation.
- (3) All complaints must be—
 - (a) either made or recorded in writing;
 - (b) acknowledged in writing within the period of 3 working days beginning with the day on which the complaint was made or, where that is not possible, as soon as reasonably practicable; and
 - (c) properly investigated.
- (4) Within the period of 10 working days beginning with the day on which the complaint was received by the person specified under sub-paragraph (2)(a) or, where that is not possible, as soon as reasonably practicable, the complainant must be given a written summary of the investigation and its conclusions.
- (5) Where the investigation of the complaint requires consideration of the patient’s medical records, the person specified under sub-paragraph (2)(a) must inform the patient or person acting on the patient’s behalf if the investigation will involve disclosure of information contained in those records to a person other than the contractor or an employee of the contractor.
- (6) The contractor must keep a record of all complaints and copies of all correspondence relating to complaints, but such records must be kept separate from patients' medical records.

Co-operation with investigations

- 87.**—(1) The contractor shall co-operate with—
- (a) any investigation of a complaint in relation to any matter reasonably connected with the provision of services under the contract undertaken by—
 - (i) the Health Board; and
 - (ii) the Scottish Public Services Ombudsman;
 - (b) any investigation of a complaint by a NHS body or local authority which relates to a patient or former patient of the contractor.
- (2) In sub-paragraph (1)—
- “NHS body” means, in Scotland, any Health Board, in England and Wales, a Primary Care trust, an NHS trust, an NHS foundation trust, a Strategic Health Authority, a Local Health Board, and, in Northern Ireland a Health and Social Services Board or a Health and Social Services trust;
- “local authority” means—
- (a) a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 (constitution of councils)⁽⁴⁸⁾;
 - (b) any of the bodies listed in section 1 of the Local Authority Social Services Act 1970 (local authorities)⁽⁴⁹⁾; or
 - (c) the Council of the Isles of Scilly.
- (3) The co-operation required by sub-paragraph (1) includes—
- (a) answering questions reasonably put to the contractor by the Health Board;

⁽⁴⁸⁾ 1994 c. 39.

⁽⁴⁹⁾ 1970 c. 42; section 1 was amended by the Local Government Act 1972 (c. 70), section 195 and by the Local Government (Wales) Act 1994 (c. 19), Schedule 10, paragraph 7.

- (b) providing any information relating to the complaint reasonably required by the Health Board; and
- (c) attending any meeting to consider the complaint (if held at a reasonably accessible place and at a reasonable hour, and due notice has been given) if the contractor's presence at the meeting is reasonably required by the Health Board.

Provision of information about complaints

88. The contractor shall inform the Health Board, at such intervals as required, of the number of complaints it has received under the procedure established in accordance with this Part.

PART 7

Dispute Resolution

Local resolution of contract disputes

89.—(1) Subject to sub-paragraph (3), in the case of any dispute arising out of or in connection with the contract, the contractor and the Health Board must make every reasonable effort to communicate and co-operate with each other with a view to resolving the dispute, before referring the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings).

(2) Either the contractor or the Health Board may, if it wishes to do so, invite the area medical committee (if any) to participate in discussions which take place pursuant to sub-paragraph (1).

(3) In the case of a dispute which falls to be dealt with under the NHS dispute resolution procedure, as modified by paragraph 36(3), sub-paragraph (1) does not apply where it is not practicable for the parties to attempt local resolution before the expiry of the period specified in paragraph 91(4) as so modified.

Dispute resolution: non-NHS contracts

90.—(1) In the case of a contract which is not an NHS contract, any dispute arising out of or in connection with the contract, except matters dealt with under the complaints procedure pursuant to Part 6 of this Schedule, may be referred for consideration and determination to the Scottish Ministers, if—

- (a) the Health Board so wishes and the contractor has agreed in writing; or
- (b) the contractor so wishes (even if the Health Board does not agree).

(2) In the case of a dispute referred to the Scottish Ministers under sub-paragraph (1)—

- (a) the procedure to be followed is the NHS dispute resolution procedure; and
- (b) the parties agree to be bound by any determination made by the adjudicator.

NHS dispute resolution procedure

91.—(1) Subject to sub-paragraph (2), the procedure specified in the following sub-paragraphs and paragraph 92 applies in the case of any dispute arising out of, or in connection with, the contract which is referred to the Scottish Ministers—

- (a) in accordance with section 17A(4) of the Act⁽⁵⁰⁾ (where the contract is a NHS contract); or

⁽⁵⁰⁾ Section 17A was inserted by the National Health Service and Community Care Act 1990 (c. 19), section 30.

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(b) in accordance with paragraph 90(1) (where the contract is not a NHS contract).

(2) In the case where—

- (a) a dispute is referred to the Scottish Ministers in accordance with regulation 9(1) (pre-contract disputes), or
- (b) a contractor (or contractors) refers a matter for determination in accordance with paragraph 36(1) or (2),

the procedure specified in the following sub-paragraphs and paragraph 92 is modified as mentioned in regulation 9 or, as the case may be, paragraph 36.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) shall send to the Scottish Ministers a written request for dispute resolution which shall include or be accompanied by—

- (a) the names and addresses of the parties to the dispute;
- (b) a copy of the contract; and
- (c) a brief statement describing the nature and circumstances of the dispute.

(4) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send the request under sub-paragraph (3) within a period of 3 years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.

(5) The Scottish Ministers may determine the dispute themselves or, if they consider it appropriate, appoint a panel consisting of three persons (referred to as “the panel”) to consider and determine the dispute.

(6) Before reaching a decision as to who should determine the dispute under sub-paragraph (5), the Scottish Ministers shall, within the period of 7 days beginning with the date on which the dispute was referred to them, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter.

(7) The Scottish Ministers shall send, with the notice given under sub-paragraph (6), to the party other than the one which referred the matter to dispute resolution, a copy of any document by which the matter was referred to dispute resolution.

(8) The Scottish Ministers shall give a copy of any representations received from a party to the other party and shall in each case request (in writing) a party to whom a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.

(9) Following receipt of any representations from the parties or, if earlier, at the end of the period for making such representations specified in the request sent under sub-paragraph (6) or (8), the Scottish Ministers shall, if they decide to appoint a panel to hear the dispute—

- (a) inform the parties in writing of the names of the persons whom they have appointed on the panel; and
- (b) pass to the panel any documents received from the parties under or pursuant to paragraph (3), (6) or (8).

(10) For the purpose of assisting it in its consideration of the matter, the adjudicator may—

- (a) invite representatives of the parties to appear before the adjudicator to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which it wishes them to give special consideration; or
- (b) consult other persons whose expertise the adjudicator considers will assist the adjudicator in the adjudicator’s consideration of the matter.

(11) Where the adjudicator consults another person under sub-paragraph (10)(b), the adjudicator shall notify the parties accordingly in writing and, where the adjudicator considers that the interests of any party might be substantially affected by the result of the consultation, the adjudicator shall give to the parties such opportunity as it considers reasonable in the circumstances to make observations on those results.

(12) In considering the matter, the adjudicator shall consider—

- (a) any written representations made in response to a request under sub-paragraph (6) but only if they are made within the specified period;
- (b) any written observations made in response to a request under sub-paragraph (8), but only if they are made within the specified period;
- (c) any oral representations made in response to an invitation under sub-paragraph (10)(a);
- (d) the results of any consultation under sub-paragraph (10)(b); and
- (e) any observations made in accordance with an opportunity given under sub-paragraph (11).

(13) In this paragraph, “specified period” means such period as the Scottish Ministers shall specify in the request sent under sub-paragraph (6) or (8), being not less than 2, nor more than 4 weeks beginning with the date on which the request is sent, but the adjudicator may, if the adjudicator considers that there is good reason for doing so, extend any such period (even after it has expired) and where it does so, a reference in this paragraph to the specified period is to the period as so extended.

(14) Subject to the other provisions of this paragraph and paragraph 92 and to any agreement by the parties, the adjudicator shall have wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

(15) Where the adjudicator is a panel, any decision or determination by the panel for the purposes of this paragraph and paragraph 92 may be by a majority.

Determination of dispute

92.—(1) The adjudicator shall record its determination, and the reasons for it, in writing and shall give notice of the determination (including the record of the reasons) to the parties and, in the case where the adjudicator is a panel, to the Scottish Ministers.

(2) Subsections (8) and (9) of section 17A of the Act (NHS contracts), as modified by regulation 10(7)(d) shall apply in the case of a determination of a reference under paragraph 90(1) as they apply in the case of a determination under subsection (4) of that section.

Interpretation of Part 7

93.—(1) In this Part, “any dispute arising out of or in connection with the contract” includes any dispute arising out of or in connection with the termination of the contract.

(2) Any term of the contract that makes provision in respect of the requirements in this Part shall survive even where the contract has terminated.

PART 8

Variation and Termination of Contracts

Variation of a contract: general

94.—(1) Subject to Schedule 2, paragraphs 62(8), 63(8) and 105 of this Schedule and paragraph 3 of Schedule 6, no amendment or variation shall have effect unless it is in writing and signed by or on behalf of the Health Board and the contractor.

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(2) In addition to the specific provision made in paragraph 105 the Health Board may vary the contract without the contractor's consent where it—

- (a) is reasonably satisfied that it is necessary to vary the contract so as to comply with the Act, any regulations made pursuant to that Act, or any direction given by the Scottish Ministers pursuant to that Act; and
- (b) notifies the contractor in writing of the wording of the proposed variation and the date upon which that variation is to take effect,

and, where it is reasonably practicable to do so, the date that the proposed variation is to take effect shall be not less than 14 days after the date on which the notice under paragraph (b) is served on the contractor.

(3) In sub-paragraph (1), “writing” does not include transmission by electronic means.

Termination by agreement

95. The Health Board and the contractor may agree in writing to terminate the contract, and if the parties so agree, they shall agree the date upon which that termination should take effect and any further terms upon which the contract should be terminated.

Termination by the contractor

96.—(1) A contractor may terminate the contract by serving notice in writing on the Health Board at any time.

(2) Where the contractor serves notice pursuant to sub-paragraph (1), the contract shall, subject to sub-paragraph (3), terminate six months after the date on which the notice is served (“the termination date”), save that if the termination date is not the last calendar day of a month, the contract shall instead terminate on the last calendar day of the month in which the termination date falls.

(3) Where the contractor is an individual medical practitioner, sub-paragraph (2) shall apply to the contractor, save that the reference to “six months” shall instead be to “three months”.

(4) This paragraph and paragraph 97 are without prejudice to any other rights to terminate the contract that the contractor may have.

Late payment notices

97.—(1) The contractor may give notice in writing (a “late payment notice”) to the Health Board if the Board has failed to make any payments due to the contractor in accordance with a term of the contract that has the effect specified in regulation 22 and the contractor shall specify in the late payment notice the payments that the Board has failed to make in accordance with that regulation.

(2) Subject to sub-paragraph (3), the contractor may, at least 28 days after having served a late payment notice, terminate the contract by a further written notice if the Health Board has still failed to make the payments due to the contractor, and that were specified in the late payment notice served on the Health Board pursuant to sub-paragraph (1).

(3) If, following receipt of a late payment notice, the Health Board refers the matter to the NHS dispute resolution procedure within 28 days of the date upon which it is served with the late payment notice, and it notifies the contractor in writing that it has done so within that period of time, the contractor may not terminate the contract pursuant to sub-paragraph (2) until—

- (a) there has been a determination of the dispute pursuant to paragraph 92 and that determination permits the contractor to terminate the contract; or
- (b) the Health Board ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

Termination by the Health Board: general

98. The Health Board may only terminate the contract in accordance with the provision in this Part.

Termination by the Health Board for breach of conditions in regulation 4

99.—(1) The Health Board shall serve notice in writing on the contractor terminating the contract forthwith if the contractor is an individual medical practitioner and the medical practitioner no longer satisfies the condition specified in regulation 4(1).

(2) Where the contractor is—

- (a) a partnership and the condition specified in regulation 4(2)(a) is no longer satisfied; or
- (b) a company limited by shares, and the condition specified in regulation 4(3)(a) is no longer satisfied,

sub-paragraph (3) shall apply.

(3) Where this sub-paragraph applies, the Health Board shall—

- (a) serve notice in writing on the contractor terminating the contract forthwith; or
- (b) serve notice in writing on the contractor confirming that the Health Board will allow the contract to continue, for a period specified by the Health Board of up to six months (the “interim period”), during which time the Health Board shall, with the consent of the contractor, employ or supply one or more general medical practitioners to the contractor for the interim period to assist the contractor in the provision of clinical services under the contract.

(4) Before deciding which of the options in sub-paragraph (3) to pursue, the Health Board shall, whenever it is reasonably practicable to do so, consult the area medical committee (if any) for its area.

(5) If the contractor does not, pursuant to sub-paragraph (3)(b), consent to the Health Board employing or supplying a general medical practitioner during the interim period, the Health Board shall serve notice in writing on the contractor terminating the contract forthwith.

(6) If, at the end of the interim period, the contractor still falls within sub-paragraph (2)(a) or (b), the Health Board shall serve notice in writing on the contractor terminating the contract forthwith.

Termination by the Health Board for the provision of untrue etc. information

100. The Health Board may serve notice in writing on the contractor terminating the contract forthwith, or from such date as may be specified in the notice if, after the contract has been entered into, it comes to the attention of the Health Board that written information provided to the Health Board by the contractor before the contract was entered into in relation to the conditions set out in regulations 4 and 5 (and compliance with those conditions) was, when given, untrue or inaccurate in a material respect.

Other grounds for termination by the Health Board

101.—(1) The Health Board may serve notice in writing on the contractor terminating the contract forthwith, or from such date as may be specified in the notice if—

- (a) in the case of a contract with a medical practitioner, that medical practitioner;
- (b) in the case of a contract with a partnership, any partner or the partnership; and
- (c) in the case of a contract with a company limited by shares—
 - (i) the company,
 - (ii) any person legally and beneficially owning a share in the company, or

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- (iii) any director or secretary of the company,
falls within sub-paragraph (2) during the existence of the contract.
- (2) A person falls within this sub-paragraph if—
- (a) the person does not satisfy the conditions prescribed in section 17L(2)(c) or (3)(b) of the Act⁽⁵¹⁾;
 - (b) the person has been or is the subject of a national disqualification;
 - (c) subject to sub-paragraph (3), the person is disqualified or suspended (other than by an interim suspension order or direction pending an investigation or a suspension on the grounds of ill-health) from practising by any licensing body anywhere in the world;
 - (d) subject to sub-paragraph (4), the person has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless before the Health Board has served a notice terminating the contract pursuant to this paragraph, the person is employed by the health service body that dismissed the person or by another health service body;
 - (e) the person is disqualified from a list unless the person's name has subsequently been included in such a list;
 - (f) the person has been convicted in the United Kingdom of murder;
 - (g) the person has been convicted in the United Kingdom of a criminal offence, other than of murder, and has been sentenced to a term of imprisonment of over six months;
 - (h) subject to sub-paragraph (5), the person has been convicted elsewhere of an offence—
 - (i) which would, if committed in Scotland, constitute murder; or
 - (ii) constitute a criminal offence other than murder, and been sentenced to a term of imprisonment of over six months;
 - (i) the person has been convicted of an offence referred to in Schedule 1 to the Criminal Procedure (Scotland) Act 1995⁽⁵²⁾ (offences against children under the age of 17 to which special provisions apply) or Schedule 1 to the Children and Young Persons Act 1933⁽⁵³⁾ (offences against children and young persons with respect to which special provisions apply);
 - (j) the person has—
 - (i) had sequestration of the person's estate awarded been adjudged bankrupt unless (in either case) the person has been discharged or the bankruptcy order has been annulled,
 - (ii) been made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986⁽⁵⁴⁾, unless that order has ceased to have effect or has been annulled,
 - (iii) made a composition or arrangement with, or granted a trust deed for, the person's creditors unless the person has been discharged in respect of it, or
 - (iv) been wound up under Part IV of the Insolvency Act 1986;
 - (k) there is—
 - (i) an administrator, administrative receiver or receiver appointed in respect of it, or

⁽⁵¹⁾ Section 17L was inserted by the 2004 Act, section 4.

⁽⁵²⁾ 1995 c. 46.

⁽⁵³⁾ 1933 c. 12 as amended by the Criminal Justice Act 1988 (c. 33), section 170, Schedule 15, paragraph 8 and Schedule 16, paragraph 16; the Sexual Offences Act 1956 (c. 69), sections 48 and 51 and Schedules 3 and 4 and as modified by the Criminal Justice Act 1988, section 170(1), Schedule 15, paragraph 9.

⁽⁵⁴⁾ 1986 c. 45. Schedule 4A was inserted by section 257 of and Schedule 2 to the Enterprise Act 2002 (c. 40).

- (ii) an administration order made in respect of it under Schedule B1 to the Insolvency Act 1986~~((55))~~;
 - (l) that person is a partnership and—
 - (i) a dissolution of the partnership is ordered by any competent court, tribunal or arbitrator, or
 - (ii) an event happens that makes it unlawful for the business of the partnership to continue, or for members of the partnership to carry on in partnership;
 - (m) the person has been—
 - (i) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990~~(56)~~ (powers of the Court of Session to deal with management of charities), from being concerned in the management or control of any body; or
 - (ii) removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commissioners or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity for which the person was responsible or to which the person was privy, or which the person by the person's conduct contributed to or facilitated;
 - (n) the person is subject to a disqualification order under the company Directors Disqualification Act 1986~~(57)~~ (failure to pay under county court administration order), the Companies (Northern Ireland) Order 1986~~(58)~~ or to an order made under section 429(2)(b) of the Insolvency Act 1986 (failure to pay under county court administration order); or
 - (o) that person has refused to comply with a request by the Health Board for that person to be medically examined on the grounds that it is concerned that the person is incapable of adequately providing services under the contract and, in a case where the contract is with a partnership or with a company, the Health Board is not satisfied that the contractor is taking adequate steps to deal with the matter; or
 - (p) the person would otherwise fall within paragraph 113(2)(e) of Schedule 6 to the National Health Service (General Medical Services Contracts) Regulations 2004~~(59)~~.
- (3) A Health Board shall not terminate the contract pursuant to sub-paragraph (2)(c) where the Health Board is satisfied that the disqualification or suspension imposed by a licensing body outside the United Kingdom does not make the person unsuitable to be—
- (a) a contractor;
 - (b) in the case of a contract with a partnership, a partner; or
 - (c) in the case of a contract with a company limited by shares—
 - (i) a person legally and beneficially holding a share in the company, or
 - (ii) a director or secretary of the company,as the case may be.
- (4) A Health Board shall not terminate the contract pursuant to sub-paragraph (2)(d)—
- (a) until a period of at least three months has elapsed since the date of the dismissal of the person concerned; or

~~(55)~~ Schedule B1 was inserted by section 248 of and Schedule 16 to the Enterprise Act 2002.

~~(56)~~ 1990 c. 40.

~~(57)~~ 1986 c. 46 as amended by the Insolvency Act 2000 (2000 c. 39).

~~(58)~~ S.I. 1986/1032 (N.I.6).

~~(59)~~ S.I. 2004/291.

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- (b) if, during the period of time specified in paragraph (a), the person concerned brings proceedings in any competent tribunal or court in respect of the person's dismissal, until proceedings before that tribunal or court are concluded,

and the Health Board may only terminate the contract at the end of the period specified in paragraph (b) if there is no finding of unfair dismissal at the end of those proceedings.

(5) A Health Board shall not terminate the contract pursuant to sub-paragraph (2)(h) where the Health Board is satisfied that the conviction does not make the person unsuitable to be—

- (a) a contractor;
- (b) in the case of a contract with a partnership a partner;
- (c) in the case of a contract with a company limited by shares—
 - (i) a person legally and beneficially holding a share in the company; or
 - (ii) a director or secretary of the company,as the case may be.

(6) In this paragraph, "health service body" does not include any person who is to be regarded as a health service body in accordance with regulation 10.

Other grounds for termination by the Health Board

102. The Health Board may serve notice in writing on the contractor terminating the contract forthwith or with effect from such date as may be specified in the notice if—

- (a) the contractor has breached the contract and, as a result of that breach, the safety of the contractor's patients is at serious risk if the contract is not terminated; or
- (b) the contractor's financial situation is such that the Health Board considers that the Health Board is at risk of material financial loss.

Termination by the Health Board: remedial notices and breach notices

103.—(1) Where a contractor has breached the contract other than as specified in paragraphs 99 to 102 and the breach is capable of remedy, the Health Board shall, before taking any action it is otherwise entitled to take by virtue of the contract, serve a notice on the contractor requiring it to remedy the breach ("remedial notice").

(2) A remedial notice shall specify—

- (a) details of the breach;
- (b) the steps the contractor must take to the satisfaction of the Health Board in order to remedy the breach; and
- (c) the period during which the steps must be taken ("the notice period").

(3) The notice period shall, unless the Health Board is satisfied that a shorter period is necessary to—

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss,

be no less than 28 days from the date that notice is given.

(4) Where a Health Board is satisfied that the contractor has not taken the required steps to remedy the breach by the end of the notice period, the Health Board may terminate the contract with effect from such date as the Health Board may specify in a further notice to the contractor.

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(5) Where a contractor has breached the contract other than as specified in paragraphs 99 to 102 and the breach is not capable of remedy, the Health Board may serve notice on the contractor requiring the contractor not to repeat the breach (“breach notice”).

(6) If, following a breach notice or a remedial notice, the contractor—

- (a) repeats the breach that was the subject of the breach notice or the remedial notice; or
- (b) otherwise breaches the contract resulting in either a remedial notice or a further breach notice,

the Health Board may serve notice on the contractor terminating the contract with effect from such date as may be specified in that notice.

(7) The Health Board shall not exercise its right to terminate the contract under sub-paragraph (6) unless it is satisfied that the cumulative effect of the breaches is such that the Health Board considers that to allow the contract to continue would be prejudicial to the efficiency of the services to be provided under the contract.

(8) If the contractor is in breach of any obligation and a breach notice or a remedial notice in respect of that default has been given to the contractor, the Health Board may withhold or deduct monies which would otherwise be payable under the contract in respect of that obligation which is the subject of the default.

Termination by the Health Board: additional provision specific to contracts with a partnership and companies limited by shares

104.—(1) Where the contractor is a company limited by shares, if the Health Board becomes aware that the contractor is carrying on any business which the Health Board considers to be detrimental to the contractor’s performance of its obligations under the contract—

- (a) the Health Board shall be entitled to give notice to the contractor requiring that it ceases carrying on that business before the end of a period of not less than 28 days beginning on the day on which the notice is given (“the notice period”); and
- (b) if the contractor has not satisfied the Health Board that it has ceased carrying on that business by the end of the notice period, the Health Board may, by a further written notice, terminate the contract forthwith or from such date as may be specified in the notice.

(2) Where the contractor is a partnership, the Health Board shall be entitled to terminate the contract by notice in writing on such dates as may be specified in that notice where one or more partners have left the practice during the existence of the contract if in its reasonable opinion, the Health Board considers that the change in membership of the partnership is likely to have a serious adverse impact on the ability of the contractor or the Health Board to perform its obligations under the contract.

(3) A notice given to the contractor pursuant to sub-paragraph (2) shall specify—

- (a) the date upon which the contract is to be terminated; and
- (b) the Health Board’s reasons for considering that the change in the membership of the partnership is likely to have a serious adverse impact on the ability of the contractor or the Health Board to perform its obligations under the contract.

Contract sanctions

105.—(1) In this paragraph and paragraph 106, “contract sanction” means—

- (a) the termination of specified reciprocal obligations under the contract;
- (b) the suspension of specified reciprocal obligations under the contract for a period of up to six months; or

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(c) the withholding or deducting of monies otherwise payable under the contract.

(2) Where the Health Board is entitled to terminate the contract pursuant to paragraph 100,101,102,103(4) or (6) or 104 , it may instead impose any of the contract sanctions if the Health Board is reasonably satisfied that the contract sanction to be imposed is appropriate and proportionate to the circumstances giving rise to the Health Board's entitlement to terminate the contract.

(3) The Health Board shall not, under sub-paragraph (2), be entitled to impose any contract sanction that has the effect of terminating or suspending any obligation to provide, or any obligation that relates to, essential services.

(4) If the Health Board decides to impose a contract sanction, it must notify the contractor of the contract sanction that it proposes to impose, the date upon which that sanction will be imposed and provide in that notice an explanation of the effect of the imposition of that sanction.

(5) Subject to paragraph 106, the Health Board shall not impose the contract sanction until at least 28 days after it has served notice on the contractor pursuant to sub-paragraph (4) unless the Health Board is satisfied that it is necessary to do so in order to—

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss.

(6) Where the Health Board imposes a contract sanction, the Health Board shall be entitled to charge the contractor the reasonable costs of additional administration that the Health Board has incurred in order to impose, or as a result of imposing, the contract sanction.

Contract sanctions and the dispute resolution procedure

106.—(1) If there is a dispute between the Health Board and the contractor in relation to a contract sanction that the Health Board is proposing to impose, the Health Board shall not, subject to sub-paragraph (4), impose the proposed contract sanction except in the circumstances specified in sub-paragraph (2)(a) or (b).

(2) If the contractor refers the dispute relating to the contract sanction to the NHS dispute resolution procedure within 28 days beginning on the date on which the Health Board served notice on the contractor in accordance with paragraph 105(4) (or such longer period as may be agreed in writing with the Health Board), and notifies the Health Board in writing that it has done so, the Health Board shall not impose the contract sanction unless—

- (a) there has been a determination of the dispute pursuant to paragraph 92 and that determination permits the Health Board to impose the contract sanction; or
- (b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(3) If the contractor does not invoke the NHS dispute resolution procedure within the time specified in sub-paragraph (2), the Health Board shall be entitled to impose the contract sanction forthwith.

(4) If the Health Board is satisfied that it is necessary to impose the contract sanction before the NHS dispute resolution procedure is concluded in order to—

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss,

the Health Board shall be entitled to impose the contract sanction forthwith, pending the outcome of that procedure.

Termination and the NHS dispute resolution procedure

107.—(1) Where the Health Board is entitled to serve written notice on the contractor terminating the contract pursuant to paragraph 100,101,102 or 103(4) or (6) the Health Board shall, in the notice served on the contractor pursuant to those provisions, specify a date on which the contract terminates that is not less than 28 days after the date on which the Health Board has served that notice on the contractor unless sub-paragraph (2) applies.

(2) This sub-paragraph applies if the Health Board is satisfied that a period less than 28 days is necessary in order to—

- (a) protect the safety of the contractor’s patients; or
- (b) protect itself from material financial loss.

(3) In a case falling within sub-paragraph (1), where the exceptions in sub-paragraph (2) do not apply, where the contractor invokes the NHS dispute resolution procedure before the end of the period of notice referred to in sub-paragraph (1), and it notifies the Health Board in writing that it has done so, the contract shall not terminate at the end of the notice period but instead shall only terminate in the circumstances specified in sub-paragraph (4).

(4) The contract shall only terminate if and when—

- (a) there has been a determination of the dispute pursuant to paragraph 92 and that determination permits the Health Board to terminate the contract; or
- (b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(5) If the Health Board is satisfied that it is necessary to impose the contract sanction before the NHS dispute resolution procedure is concluded in order to—

- (a) protect the safety of the contractor’s patients; or
- (b) protect itself from material financial loss,

sub-paragraphs (3) and (4) shall not apply and the Health Board shall be entitled to confirm, by written notice to be served on the contractor, that the contract will nevertheless terminate at the end of the period of the notice it served pursuant to paragraph 100,101,102,103(4) or (6) or 104.

Consultation with the area medical committee

108.—(1) Whenever the Health Board is considering—

- (a) terminating the contract pursuant to paragraph 100,101,102,103(4) or (6) or 104;
- (b) imposing a contract sanction,

it shall, whenever it is reasonably practicable to do so, consult the area medical committee for its area before it terminates the contract or imposes a contract sanction.

(2) Whether or not the area medical committee has been consulted pursuant to sub-paragraph (1), whenever the Health Board imposes a contract sanction on a contractor or terminates a contract pursuant to this Part, it shall, as soon as reasonably practicable, notify the area medical committee in writing of the contract sanction imposed or of the termination of the contract (as the case may be).

Where the contractor changes from being an individual to a partnership

109.—(1) If—

- (a) a contractor is an individual medical practitioner who proposes to practise in partnership (“the proposed partnership”) with one or more persons (“the proposed partners”);

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- (b) the proposed partners propose that the proposed partnership should enter into a new contract (“the new contract”) with the Health Board on as similar terms as possible to the contractor’s contract (“the old contract”) and, as a consequence;
- (c) the contractor proposes to terminate the old contract,

the contractor and the proposed partners may give written notice of those matters to the Health Board which shall state—

- (i) the name and address of the proposed partnership and of the proposed partners;
- (ii) the date on which it is proposed that the partnership should be formed and become the contractor, which shall not be less than 28 days after the date of service of the notice;
- (iii) that when the proposed partnership is formed, the requirements of regulations 4(2) and 5(1)(b) will be satisfied; and
- (iv) whether or not the proposed partnership is to be a limited partnership and, if so, who will be a limited and who a general partner,

and the notice shall be signed by the contractor and by the proposed partners as proposed partners of the proposed partnership.

(2) If the Health Board is satisfied as to the accuracy of the matters specified in the notice under sub-paragraph (1), it shall give written notice to the contractor and the proposed partners that it is prepared—

- (a) to terminate the old contract with effect from a specified date; and
- (b) to enter into a new contract with the proposed partnership with effect from that date which shall be on the same terms as the old contract, with only such changes as are necessary to reflect the fact that the contractor will be a partnership and not an individual medical practitioner,

and the notice shall specify the changes which the Health Board considers are necessary in terms of paragraph (b).

(3) Where it is reasonably practicable, the date specified by the Health Board in the notice under sub-paragraph (2) shall be the date proposed in the notice served under sub-paragraph (1) or, where that date is not reasonably practicable, the date specified shall be a date after that proposed date that is as close to it as is reasonably practicable.

(4) If the contractor and the proposed partners agree with what is contained in the notice by the Health Board under sub-paragraph (2)—

- (a) the Health Board and the contractor shall agree in writing to terminate the old contract with effect from the date specified in that notice; and
- (b) the Health Board and the partnership shall enter into a new contract with the Health Board with effect from that date on the terms mentioned in paragraph (b) of that sub-paragraph but subject to the changes specified in that notice.

(5) This paragraph is without prejudice to any other way in which the old contract may be terminated and a new contract entered into with the partnership.

Where the contractor changes from being a partnership to an individual

110.—(1) If a contractor is a partnership which it is proposed will be terminated or dissolved and as a consequence the contractor’s contract (“the old contract”) will be terminated and one of the partners wishes to enter into a new contract (“the new contract”) with the Health Board as an individual medical practitioner (“the proposed contractor”) on as similar terms as possible as the old contract, the partnership and the proposed contractor may give written notice thereof to the Health Board which shall state—

(a) the name and address of the partnership, of the partners in that partnership and of the proposed contractor;

(b) the date on which it is proposed that the proposed contractor should become the contractor, which shall not be less than 28 days after the date of service of the notice; and

(c) that the proposed contractor meets the requirements of regulations 4(1) and 5(1)(a),

and the notice shall be signed by the partnership, the partners in that partnership and the proposed contractor.

(2) If the Health Board is satisfied as to the accuracy of the matters specified in the notice under sub-paragraph (1), it shall give written notice to the partnership and the proposed contractor that it is prepared—

- (a) to terminate the old contract with effect from a specified date; and
- (b) to enter into a new contract with the proposed contractor with effect from that date which shall be on the same terms as the old contract, with only such changes as are necessary to reflect the fact that the contractor will be an individual medical practitioner and not a partnership,

and the notice shall specify the changes which the Health Board consider are necessary in terms of paragraph (b).

(3) Where it is reasonably practicable, the date specified by the Health Board in the notice under sub-paragraph (2) shall be the date proposed in the notice served under sub-paragraph (1) or, where that date is not reasonably practicable, the date specified shall be a date after that proposed date that is as close to it as is reasonably practicable.

(4) If the partnership and the proposed contractor agree with what is contained in the notice by the Health Board under sub-paragraph (2)—

- (a) the Health Board and the partnership shall agree in writing to terminate the old contract with effect from the date specified in that notice; and
- (b) the Health Board and the proposed contractor shall enter into a new contract with the Health Board with effect from that date on the terms mentioned in paragraph (b) of that sub-paragraph but subject to the changes specified in that notice.

(5) This paragraph is without prejudice to any other way in which the old contract may be terminated and a new contract entered into with the proposed contractor.

PART 9

MISCELLANEOUS

Clinical governance

111.—(1) The contractor shall have an effective system of clinical governance.

(2) The contractor shall nominate a person who will have responsibility for ensuring the effective operation of a system of clinical governance.

(3) The person nominated under sub-paragraph (2) shall be a person who performs or manages services under the contract.

(4) In this paragraph “system of clinical governance” means a framework through which the contractor endeavours continuously to improve the quality of its service and safeguard high standards of care by creating an environment in which clinical excellence can flourish.

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Insurance

112.—(1) The contractor shall at all times hold adequate insurance against liability arising from negligent performance of clinical services under the contract.

(2) The contractor shall not sub-contract its obligations to provide clinical services under the contract unless it has satisfied itself that the sub-contractor holds adequate insurance against liability arising from negligent performance of such services.

(3) In this paragraph—

- (a) “insurance” means a contract of insurance or other arrangement made for the purpose of indemnifying the contractor; and
- (b) a contractor shall be regarded as holding insurance if the insurance is held by an employee of the contractor in connection with clinical services which that employee provides under the contract or, as the case may be, sub-contract.

Insurance

113. The contractor shall at all times hold adequate public liability insurance in relation to liabilities to third parties arising under or in connection with the contract which are not covered by the insurance referred to in paragraph 112.

Gifts

114.—(1) The contractor shall keep a register of gifts which—

- (a) are given to any of the persons specified in sub-paragraph (2) by or on behalf of—
 - (i) a patient,
 - (ii) a relative of a patient, or
 - (iii) any person who provides or wishes to provide services to the contractor or its patients in connection with the contract; and
- (b) have, in its reasonable opinion, an individual value of more than £100.00.

(2) The persons referred to in sub-paragraph (1) are—

- (a) the contractor;
- (b) where the contract is with a partnership, any partner;
- (c) where the contract is with a company—
 - (i) any person legally and beneficially holding a share in the company, or
 - (ii) a director or secretary of the company;
- (d) any person employed by the contractor for the purposes of the contract;
- (e) any general medical practitioner engaged by the contractor for the purposes of the contract;
- (f) any spouse of a contractor (where the contractor is an individual medical practitioner) or of a person specified in paragraphs (b) to (e); or
- (g) any person (whether or not of the opposite sex) whose relationship with a contractor (where the contractor is an individual medical practitioner) or with a person specified in paragraphs (b) to (e) has the characteristics of the relationship between husband and wife.

(3) Sub-paragraph (1) does not apply where—

- (a) there are reasonable grounds for believing that the gift is unconnected with services provided or to be provided by the contractor;
- (b) the contractor is not aware of the gift; or

- (c) the contractor is not aware that the donor wishes to provide services to the contractor.
- (4) The contractor shall take reasonable steps to ensure that it is informed of gifts which fall within sub-paragraph (1) and which are given to the persons specified in sub-paragraph (2)(b) to (g).
- (5) The register referred to in sub-paragraph (1) shall include the following information:—
 - (a) the name of the donor;
 - (b) in a case where the donor is a patient, the patient’s National Health Service number or, if the number is not known, his address;
 - (c) in any other case, the address of the donor;
 - (d) the nature of the gift;
 - (e) the estimated value of the gift; and
 - (f) the name of the person or persons who received the gift.
- (6) The contractor shall make the register available to the Health Board on request.

Compliance with legislation and guidance

- 115.** The contractor shall—
- (a) comply with all relevant legislation; and
 - (b) have regard to all relevant guidance issued by the Health Board and the Scottish Ministers.

Third party rights

- 116.** The contract shall not create any right enforceable by any person not a party to it.

SCHEDULE 6

Regulation 32

OUT OF HOURS SERVICES

Temporary arrangements for transfer of obligations and liabilities in relation to certain out of hours services

- 1.—(1)** In this Schedule—

“out of hours arrangement” means an arrangement under sub-paragraph (2); and

“transferee out of hours services provider” means a person referred to in sub-paragraph (5) who has undertaken to carry out the obligations of a contractor during all or part of the out of hours period in accordance with an out of hours arrangement referred to in sub-paragraph (2).

(2) Subject to the provisions of this Schedule, where a contractor is required to provide out of hours services pursuant to regulation 30 or 31, the contractor may, with the approval of the Health Board, make an arrangement with a person referred to in sub-paragraph (5) to transfer the contractor’s obligations under these regulations.

- (3) Any arrangement made pursuant to sub-paragraph (2) shall cease to have effect—

- (a) on the day when the transferee out of hours service provider ceases to meet any of the conditions required to provide primary medical services under these Regulations; or
- (b) on 1st January 2005,

whichever is the earlier.

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(4) An arrangement made in accordance with sub-paragraph (2) shall, for so long as it continues, relieve the contractor of—

- (a) its obligations to provide out of hours services pursuant to regulation 30 or 31; and
- (b) all liabilities under the contract in respect of those services.

(5) The person referred to in this sub-paragraph is any person who holds a general medical services contract or section 17C agreement with the Health Board which includes the provision of out of hours services.

(6) A contractor may make more than one out of hours arrangement and may do so (for example) with different contractors or providers of primary medical services and in respect of different patients, different times and different parts of its practice area.

(7) A contractor may retain responsibility for, or make separate out of hours arrangements in respect of, the provision to any patients of maternity medical services during the out of hours period which the contractor is required to provide pursuant to regulation 30 or 31 and any separate out of hours arrangements it makes may encompass all or any part of the maternity medical services it provides.

(8) Nothing in this paragraph prevents a contractor from retaining or resuming its obligations in relation to named patients.

Application for approval of an out of hours arrangement

2.—(1) An application to the Health Board for approval of an out of hours arrangement shall be made in writing and shall state—

- (a) the name and address of the proposed transferee out of hours service provider;
- (b) the periods during which the contractor's obligations under the contract are to be transferred;
- (c) how the proposed transferee out of hours service provider intends to meet the contractor's obligations during the periods specified under paragraph (b);
- (d) the arrangements for the transfer of the contractor's obligations under the contract to and from the transferee out of hours service provider at the beginning and end of the periods specified under paragraph (b);
- (e) whether the proposed arrangement includes the contractor's obligations in respect of maternity medical services; and
- (f) how long the proposed arrangements are intended to last and the circumstances in which the contractor's obligations under the contract during the periods specified under paragraph (b) would revert to it.

(2) The Health Board shall determine the application before the end of the period of 28 days beginning with the day on which the Health Board received it.

(3) The Health Board shall grant approval to a proposed out of hours arrangement if it is satisfied—

- (a) having regard to the overall provision of primary medical services provided in the out of hours period in its area, that the arrangement is reasonable and will contribute to the efficient provision of such services in the area;
- (b) having regard, in particular, to the interests of the contractor's patients, that the arrangement is reasonable;
- (c) having regard, in particular, to all reasonably foreseeable circumstances, that the arrangement is practicable and will work satisfactorily;

- (d) that it will be clear to the contractor's patients how to seek primary medical services during the out of hours period;
- (e) where maternity medical services are to be provided under the out of hours arrangement, that they will be performed by a medical practitioner who has such medical experience and training as are necessary to enable the medical practitioner properly to perform such services; and
- (f) that if the arrangement comes to an end, the contractor has in place proper arrangements for the immediate resumption of the contractor's responsibilities,

and shall not refuse to grant approval without first consulting the area medical committee (if any) for its area.

(4) The Health Board shall give notice to the contractor of its determination and, where it refuses an application, it shall send the contractor a statement in writing of the reasons for its determination.

(5) A contractor which wishes to refer the matter in accordance with the NHS dispute resolution procedure must do so before the end of the period of 30 days beginning with the day on which the Health Board's notification under sub-paragraph (4) was sent.

Effect of approval of an arrangement with a transferee out of hours service provider

3. Where the Health Board has approved an out of hours arrangement with a transferee out of hours service provider, the Health Board and the transferee out of hours service provider shall be deemed to have agreed a variation of their contract which has the effect of including in it, from the date on which the out of hours arrangement commences, and for so long as that arrangement continues, the services covered by that arrangement and paragraph 94(1) of Schedule 5 shall not apply.

Review of approval

4.—(1) Where it appears to the Health Board that it may no longer be satisfied of any of the matters referred to in paragraph 2(3), it may give notice to the contractor that it proposes to review its approval of the out of hours arrangement.

(2) On any review under sub-paragraph (1), the Health Board shall allow the contractor a period of 30 days, beginning with the day on which it sent the notice, within which to make representations in writing to the Health Board.

(3) After considering any representations made in accordance with sub-paragraph (2), the Health Board may determine to—

- (a) continue its approval;
- (b) withdraw its approval following a period of notice; or
- (c) if it appears to it that it is necessary in the interests of the contractor's patients, withdraw its approval immediately.

(4) Except in the case of an immediate withdrawal of approval, the Health Board shall not withdraw its approval without first consulting the area medical committee for its area.

(5) Where the Health Board determines to withdraw its approval immediately, it shall notify the area medical committee (if any) for its area.

(6) The Health Board shall give notice to the contractor of its determination under sub-paragraph (3).

(7) Where the Health Board withdraws its approval, whether immediately or on notice, it shall include with the notice a statement in writing of the reasons for its determination.

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(8) A contractor which wishes to refer the matter in accordance with the NHS dispute resolution procedure must do so before the end of the period of 30 days beginning with the day on which the Health Board's notification under sub-paragraph (6) was sent.

(9) Where the Health Board determines to withdraw its approval following a period of notice, the withdrawal shall take effect at the end of the period of two months beginning with—

- (a) the date on which the notice referred to in sub-paragraph (6) was sent; or
- (b) where there has been a dispute which has been referred under the NHS dispute resolution procedure and the dispute is determined in favour of withdrawal, the date on which the contractor receives notice of the determination.

(10) Where the Health Board determines to withdraw its approval immediately, the withdrawal shall take effect on the day on which the notice referred to in sub-paragraph (6) is received by the contractor.

Immediate withdrawal of approval other than following review

5.—(1) The Health Board shall withdraw its approval of an out of hours arrangement immediately—

- (a) in the case of an arrangement with a person referred to in paragraph 1(5), if the person with whom it is made ceases to hold a contract or section 17C agreement for the provision of primary medical services with the Health Board which includes the provision of out of hours services; or
- (b) where, without any review having taken place under paragraph 4, it appears to the Health Board that it is necessary in the interests of the contractor's patients to withdraw its approval immediately.

(2) The Health Board shall give notice to the contractor of a withdrawal of approval under sub-paragraph (1)(a) or (b) and shall include with the notice a statement in writing of the reasons for its determination.

(3) An immediate withdrawal of approval under sub-paragraph (1) shall take effect on the day on which the notice referred to in sub-paragraph (2) is received by the contractor.

(4) The Health Board shall notify the area medical committee for its area of a withdrawal of approval under sub-paragraph (1)(b).

(5) A contractor which wishes to refer a withdrawal of approval under sub-paragraph (1)(b) in accordance with the NHS dispute resolution procedure must do so before the end of the period of 30 days beginning with the day on which the Health Board's notification under sub paragraph (2) was sent.

Termination of an out of hours arrangement

6. The contractor shall terminate an out of hours arrangement with effect from the date of the taking effect of the withdrawal of the Health Board's approval of that arrangement under paragraph 4 or 5.

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- (b) the names of all the partners and, in the case of a limited partnership, their status as a general or limited partner.
- 3. In the case of a contract with a company—
 - (a) the names of the directors, the company secretary and the shareholders of that company; and
 - (b) the address of the company's registered office.
- 4. The full name of each person performing services under the contract.
- 5. In the case of each health care professional performing services under the contract the health care professional's professional qualifications.
- 6. Whether the contractor undertakes the teaching or training of health care professionals or persons intending to become health care professionals.
- 7. The contractor's practice area, by reference to a sketch diagram, plan or postcode.
- 8. The address of each of the practice premises.
- 9. The contractor's telephone and fax numbers and the address of the contractor's website (if any).
- 10. Whether the practice premises have suitable access for all disabled patients and, if not, the alternative arrangements for providing services to such patients.
- 11. How to register as a patient.
- 12. The right of patients to express a preference of practitioner in accordance with paragraph 18 of Schedule 5 and the means of expressing such a preference.
- 13. The services available under the contract.
- 14. The opening hours of the practice premises and the method of obtaining access to services throughout the core hours.
- 15. The criteria for home visits and the method of obtaining such a visit.
- 16. The consultations available to patients under paragraphs 5 and 6 of Schedule 5.
- 17. The arrangements for services in the out of hours period (whether or not provided by the contractor) and how the patient may contact such services.
- 18. If the services in paragraph 17 are not provided by the contractor, the fact that the Health Board referred to in paragraph 28 is responsible for commissioning the services.
- 19. The telephone number of NHS 24 and details of the NHS 24 website.
- 20. The method by which patients are to obtain repeat prescriptions.
- 21. If the contractor is a dispensing contractor the arrangements for dispensing prescriptions.
- 22. How patients may make a complaint or comment on the provision of service.
- 23. The rights and responsibilities of the patient, including keeping appointments.
- 24. The action that may be taken where a patient is violent or abusive to the contractor, the contractor's staff, persons present on the practice premises or in the place where treatment is provided under the contract or other persons specified in paragraph 21(2) of Schedule 5.
- 25. Details of who has access to patient information (including information from which the identity of the individual can be ascertained) and the patient's rights in relation to disclosure of such information.

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26. The name, address and telephone number of the Health Board which is a party to the contract and from whom details of primary medical services in the area may be obtained.