

SCHEDULE 5

Regulation 18

OTHER CONTRACTUAL TERMS

PART 1

PROVISION OF SERVICES

Services to registered patients

1. Where the agreement provides for a contractor to provide essential services, the contractor must—

- (a) provide those services and such other services that it is required to provide to those patients, at such times, within core hours, as are appropriate to meet the reasonable needs of its patients; and
- (b) have in place arrangements for its patients to access such services throughout the core hours in case of emergency.

Premises

2. Subject to any plan which is included in the agreement for bringing the contractor's premises up to the required standard, the contractor shall ensure that the premises used for the provision of services under the agreement 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

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

- (a) has not previously made an appointment; and
- (b) attends at the contractor's 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) he is then offered an appointment to attend again within a time which is appropriate and reasonable having regard to all the circumstances and his health would not thereby be jeopardised.

Attendance outside practice premises

4.—(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 him to attend at the contractor's premises,

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

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

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- (a) the place recorded in the patient's medical records as being his last home address;
 - (b) such other place as the contractor has informed the patient (and the relevant body) is the place where it 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.

Clinical reports

5.—(1) Subject to sub-paragraph (4), where the contractor provides any clinical services, other than under a private arrangement, to a patient who is not on its list of patients it shall prepare a clinical report relating to the consultation, and any treatment provided.

(2) Subject to sub-paragraph (4), the contractor (other than a Primary Care Trust) shall as soon as reasonably practicable, provide a copy of the clinical report to the relevant body.

(3) The relevant body shall send any report prepared by it under sub-paragraph (1) or received by it under sub-paragraph (2)—

- (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 Primary Care Trust, Local Health Board, Health Board or Health and Social Services Board, in whose area the patient is resident unless it is that Primary Care Trust.

(4) This paragraph does not apply in relation to out of hours services provided by a contractor which is required pursuant to paragraph 9 to comply with the quality standards referred to in that paragraph.

Storage of vaccines

6. 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

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

Criteria for out of hours services

8. Except to the extent that the agreement otherwise provides, a contractor whose agreement 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 he could obtain such services during core hours.

Standards for out of hours services

9.—(1) A contractor which provides out of hours services to registered patients of another contractor or provider of essential services (or their equivalent) and who does not fall within sub-paragraph (2), must, in the provision of out of hours services, meet the quality standards set out in the document entitled “Quality Standards in the Delivery of GP Out of Hours Services” published on 20th June 2002⁽¹⁾.

(2) A contractor which has contracted to provide out of hours services only to patients which it provides essential services to under the agreement, must from 1st January 2005, in the provision of such out of hours services, meet the quality standards set out in the document entitled “Quality Standards in the Delivery of GP Out of Hours Services” published on 20th June 2002.

Duty of co-operation

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

- (a) a particular service; or
- (b) 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 in so far as 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 relevant body 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 contractor’s 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 agreement does not include the provision of out of hours services to make itself available during the out of hours period.

11. Where a contractor is to cease to be required to provide to its patients—

- (a) a particular service; or
- (b) 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 relevant body or by any person with whom the relevant body intends to enter into an agreement, general medical services contract or other contract for the provision of such services or any Primary Care Trust in whose area its registered patients reside.

PART 2

PATIENTS

General Provision

12.—(1) This Part shall apply to contractors which provide essential services.

(1) The document “Quality Standards in the delivery of GP Out of Hours Services” published on 20th June 2002 is published by the Department of Health on its website at www.doh.gov.uk/pricare/qualitystandards.htm or a copy may be obtained by writing to Primary Care, Room 7E28, Department of Health, Quarry House, Quarry Hill, Leeds LS2 7UE or by e-mailing OOHAccreditation@doh.gov.uk.

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(2) Where the contractor is a Primary Care Trust which provides essential services under the agreement this Part shall apply as modified in accordance with Schedule 7.

List of patients

13. Where the agreement requires the contractor to provide essential services, the Primary Care Trust 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 14 and who have not subsequently been removed from that list under paragraphs 18 to 26; and
- (b) who have been assigned to the contractor under paragraph 31 or 32 and whose assignment has not subsequently been rescinded.

Application for inclusion in a list of patients

14.—(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 contractor's premises a medical card or an application signed (in either case) by the applicant or a person authorised by the applicant to sign on his 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 who has care of the child,
 - (ii) by a person duly authorised by a local authority to whose care the child has been committed under the Children Act 1989(2), 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 a relative or the primary carer of that person.

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

(6) On receipt of a notice under sub-paragraph (5), the Primary Care Trust 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.

(2) 1989 c. 41.

Temporary residents

15.—(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 his normal place of residence and is not being provided with essential services (or their equivalent) under any other arrangement in the locality where he 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 he arrives in that place, he 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 him as a patient,

shall notify him 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 Primary Care Trust in writing of any person whom it accepted as a temporary resident.

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

16.—(1) The contractor shall only refuse an application made under paragraph 14 or 15 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 14, 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 14 or 15 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 14 and of the reasons for them and shall make this record available to the Primary Care Trust on request.

Patient preference of practitioner

17.—(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

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- (b) does not routinely perform the service in question under the agreement on behalf of the contractor.

Removal from the list at the request of the patient

18.—(1) The contractor shall notify the Primary Care Trust in writing of any request for removal from its list of patients received from a registered patient.

(2) Where the Primary Care Trust—

- (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 Primary Care Trust receives 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 Primary Care Trust,

whichever is the sooner.

(4) The Primary Care Trust 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 19(1)(b) and (9), 20(6) and (7), 22(1), 25(2) and 27(3), 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 14(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.

Removals from the list at the request of the contractor

19.—(1) Subject to paragraph 20, 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—

- (a) notify the Primary Care Trust 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 specified in sub-paragraph (4), a contractor may only request a removal under sub-paragraph (1), if within the period of 12 months prior to the date of its request to the Primary Care Trust, it has warned the patient that he 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 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 any party to the agreement who is an individual, any member of the contractor's staff or any other person; or
- (c) it is, in the opinion of the contractor, not reasonable or practical for a warning to be given.

(5) 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.

(6) 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 Primary Care Trust on request.

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

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

whichever is the sooner.

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

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

whichever is the sooner.

(9) The Primary Care Trust shall notify in writing—

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

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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 (7) or (8).

Removals from the list of patients who are violent

20.—(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 his safety; and
- (b) it has reported the incident to the police,

shall notify the Primary Care Trust in accordance with sub-paragraph (3).

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

- (a) any party to the agreement who is an individual;
- (b) any member of the contractor's staff; or
- (c) any other person present—
 - (i) on the contractor's premises, or
 - (ii) in the place where services were provided to the patient under the agreement.

(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 seven days (and for this purpose a faxed notification is not a written one).

(4) The Primary Care Trust 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 Primary Care Trust; or
- (b) sends or delivers the notification to the Primary Care Trust.

(6) Where, pursuant to this paragraph, the contractor has notified the Primary Care Trust that it wishes to have a patient removed from its 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 any party to the agreement who is an individual, a member of the contractor's staff or any other person.

(7) Where the Primary Care Trust 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 his removal.

Removals from the list of patients registered elsewhere

21.—(1) The Primary Care Trust shall remove a patient from the contractor's list of patients if—

- (a) he has subsequently been registered with another provider of essential services (or their equivalent) in the area of the Primary Care Trust; or

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- (b) it has received notice from another Primary Care Trust, a Local Health Board, a Health Board or a Health and Social Services Board that he has subsequently been registered with a provider of essential services (or their equivalent) outside the area of the Primary Care Trust.
- (2) A removal in accordance with sub-paragraph (1) shall take effect—
 - (a) on the date on which the Primary Care Trust receives notification of the registration of the person with the new provider; or
 - (b) with the consent of the Primary Care Trust, on such other date as has been agreed between the contractor and the new provider.
- (3) The Primary Care Trust shall notify the contractor in writing of persons removed from its list of patients under sub-paragraph (1).

Removals from the list of patients who have moved

22.—(1) Subject to sub-paragraph (2), where the Primary Care Trust 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 Primary Care Trust shall—

- (a) inform that patient and the contractor that the contractor is no longer obliged to visit and treat him;
- (b) advise the patient in writing either to obtain the contractor’s agreement to his continued inclusion in the contractor’s list of patients or to apply for registration with another provider of essential services (or their equivalent); and
- (c) inform him that if, after the expiration of 30 days from the date of the advice mentioned in paragraph (b), he has not acted in accordance with the advice and informed it accordingly, the Primary Care Trust will remove him 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 Primary Care Trust has not been notified of the action taken, it shall remove the patient from the contractor’s list of patients and inform him and the contractor accordingly.

23. Where the address of a patient who is on the contractor’s list of patients is no longer known to the Primary Care Trust, the Primary Care Trust 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 Primary Care Trust that it is still responsible for providing essential services to that patient.

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

24.—(1) The Primary Care Trust 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) is serving a prison sentence of more than two years or sentences totalling in the aggregate more than that period;
- (d) has been absent from the United Kingdom for a period of more than three months; or
- (e) has died.

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- (2) A removal in accordance with sub-paragraph (1) shall take effect—
 - (a) in the cases referred to in sub-paragraph (1)(a) to (c) from the date of the departure, enlistment or imprisonment or the date on which the Primary Care Trust first receives notification of the departure, enlistment or imprisonment whichever is the later; or
 - (b) in the cases referred to in sub-paragraph (1)(d) and (e) from the date on which the Primary Care Trust first receives notification of the absence or death.
- (3) The Primary Care Trust 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

- 25.**—(1) The Primary Care Trust 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 patient’s stay in the place of temporary residence has exceeded three months; and
 - (b) that he has not returned to his normal place of residence or any other place within the contractor’s practice area.
- (2) The Primary Care Trust 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 him of—
- (a) his entitlement to make arrangements for the provision to him of essential services (or their equivalent), including by the contractor by which he has been treated as a temporary resident; and
 - (b) the name and address of the Primary Care Trust in whose area he is resident.

Removals from a list of pupils etc of a school

- 26.**—(1) Where the contractor provides essential services under the agreement to persons on the grounds that they are pupils at or staff or residents of a school, the Primary Care Trust 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 resident of that school provided by that school.
- (2) Where the Primary Care Trust 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 Primary Care Trust 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

- 27.**—(1) Where the 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,
 - (ii) from a person whom it has not accepted as a temporary resident, or
 - (iii) on behalf of a person mentioned in sub-paragraph (i) or (ii), from one of the persons specified in paragraph 14(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 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 he 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 him 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 Primary Care Trust 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 20(1); or
 - (b) in all other cases, 14 days from the date on which the notice is given.

Closure of lists of patients

28.—(1) A contractor which wishes to close its list of patients shall notify the Primary Care Trust 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 Primary Care Trust shall enter into discussions with the contractor concerning the support which the Primary Care Trust may give the contractor, or other changes which the Primary Care Trust 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 Primary Care Trust'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 Primary Care Trust and the contractor reach agreement that the contractor's list of patients should remain open, the Primary Care Trust shall send full details of the agreement in writing to the contractor.

(6) The Primary Care Trust 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 Primary Care Trust and the contractor reach agreement that the contractor's list of patients should close; or

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- (b) the Primary Care Trust and the contractor fail to reach agreement and the contractor still wishes to close its list of patients,

the contractor shall send a closure notice to the Primary Care Trust.

(8) A closure notice shall be submitted in the form specified in Schedule 8, 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 12 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 from or reduction in provision of any service which had previously been provided under the agreement.

(9) The Primary Care Trust shall forthwith acknowledge receipt of the closure notice in writing to the contractor.

(10) Before the Primary Care Trust reaches a decision as to whether to approve or reject the closure notice under sub-paragraph (12), the Primary Care Trust and the contractor may enter into further discussions concerning the details of the closure notice referred to 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 12 months.

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

(12) Within a period of 14 days beginning with the date of receipt of the closure notice, the Primary Care Trust 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

29.—(1) If the Primary Care Trust approves the closure notice in accordance with paragraph 28(12)(a), the contractor shall close its list of patients—

- (a) with effect from a date agreed between the Primary Care Trust 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 Primary Care Trust's decision to approve the closure notice.

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(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 28(8)(a) (or, where the period of 12 months specified in paragraph 28(10) applies, 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 28(8)(c); or
- (b) the Primary Care Trust 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 28(8)(a) (or, where the period of 12 months specified in paragraph 28(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 28(8)(d).

(5) Except in cases where the contractor's list of patients is already open pursuant to sub-paragraph (3), the Primary Care Trust shall notify the contractor in writing between seven and fourteen 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 28(8) have been revised following discussions under paragraph 28(10), references in this paragraph to details specified in the closure notice are references to those details as so revised.

Rejection of closure notice

30.—(1) This regulation applies where the Primary Care Trust rejects the closure notice in accordance with paragraph 28(12) (b).

(2) The contractor and the Primary Care Trust 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 Primary Care Trust must ensure that the assessment panel is appointed 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 it should be permitted to do so.

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

(5) The members of the assessment panel shall be—

- (a) the Chief Executive of the Primary Care Trust of which the assessment panel is a committee or sub-committee;
- (b) a person representative of patients in an area other than that of the Primary Care Trust which is a party to the agreement; and
- (c) a general medical practitioner or other person who, in the opinion of the Primary Care Trust of which the assessment panel is a committee or sub-committee, is representative of the interests of contractors provided that the practitioner or other person which is a party to the agreement does not practise or work within the area of the Primary Care Trust.

(6) At least one member of the assessment panel shall visit the contractor before reaching a determination under sub-paragraph (7).

(7) Within the period of 28 days beginning with the date on which the Primary Care Trust rejected the closure notice, the assessment panel shall—

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

and shall notify the Primary Care Trust and the contractor of its determination in writing as soon as possible.

(8) Where the assessment panel determines in accordance with sub-paragraph (7)(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 28(8)(a) to (d).

(9) Where the assessment panel determines in accordance with sub-paragraph (7)(b) that the contractor's list of patients may not close, that list shall remain open, and the Primary Care Trust and the contractor shall enter into discussions with a view to ensuring that the contractor receives support from the Primary Care Trust which will enable it to continue to provide services safely and effectively.

(10) Where the assessment panel determines in accordance with sub-paragraph (7)(b) that the contractor's list of patients may not close, the contractor may not submit a further closure notice as described in paragraph 28 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 agreement.

Assignment of patients to lists: open lists

31.—(1) A Primary Care Trust may, subject to paragraph 33, assign a new patient to a contractor whose list of patients is open.

- (2) In this paragraph and in paragraphs 32 and 34 to 36, a “new” patient means a person who—
 - (a) is resident (whether or not temporarily) within the area of the Primary Care Trust;
 - (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

32.—(1) A Primary Care Trust 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 Primary Care Trust may, subject to paragraph 33, assign a new patient to a contractor whose practice premises are within the Primary Care Trust'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 Primary Care Trust's area have closed their lists of patients;
- (b) the assessment panel has determined under paragraph 34(7) that patients may be assigned to the contractor in question, and that determination has not been overturned either by a

determination of the Secretary of State under paragraph 35(13) or (where applicable) by a court; and

- (c) the Primary Care Trust has entered into discussions with the contractor in question regarding the assignment of a patient if such discussions are required under paragraph 36.

Factors relevant to assignments

33. In making an assignment to a contractor under paragraph 31 or 32, the Primary Care Trust 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 Primary Care Trust, the patient's name has been removed from the list of patients of any contractor or other provider of essential services (or their equivalent) in the area of the Primary Care Trust under paragraph 19 or its equivalent provision applying in relation to that contractor;
- (d) whether the patient's name has been removed from the list of patients of any contractor or other provider of essential services (or their equivalent) in the area of the Primary Care Trust under paragraph 20 or its equivalent provision applying in relation to that contractor and, if so, whether the contractor has appropriate facilities to deal with such a patient; and
- (e) such other matters as the Primary Care Trust considers to be relevant.

Assignments to closed lists: determinations of the assessment panel

34.—(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 Primary Care Trust have closed their lists of patients.

(2) If the Primary Care Trust 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 which must include details of those contractors to which the Primary Care Trust wishes to assign patients.

(3) The Primary Care Trust must ensure that the assessment panel is appointed to consider and determine its proposal made under sub-paragraph (2), and the composition of the assessment panel shall be as described in paragraph 30(5).

(4) The Primary Care Trust shall notify in writing—

- (a) the relevant Strategic Health Authority; and
- (b) contractors or general medical services contractors whose practice premises are within the Primary Care Trust's area which—
 - (i) have closed their list of patients, and
 - (ii) may, in the opinion of the Primary Care Trust, be affected by the determination of the assessment panel,

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 Primary Care Trust 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

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- (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 Primary Care Trust may assign patients to contractors which have closed their lists of patients; and if it determines that the Primary Care Trust may make such assignments, it shall also determine those contractors to which patients may be assigned.
- (8) The assessment panel may determine that the Primary Care Trust may assign patients to contractors other than those contractors specified by the Primary Care Trust in its proposal under sub-paragraph (2), as long as the contractors were notified under sub-paragraph (4)(b).
- (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—
 - (a) the Primary Care Trust;
 - (b) the relevant Strategic Health Authority; and
 - (c) those contractors which were notified under sub-paragraph (4)(b).

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

- 35.**—(1) Where an assessment panel makes a determination under paragraph 34(7) that the Primary Care Trust 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 Secretary of State to review the determination of the assessment panel.
- (2) Where a matter is referred to the Secretary of State in accordance with sub-paragraph (1), it shall be reviewed in accordance with the procedure specified in the following sub-paragraphs.
- (3) Where more than one contractor specified in the determination in accordance with paragraph 34(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 Secretary of State shall review the matter in relation to those contractors together.
- (4) Within the period of 7 days beginning with the date of the determination by the assessment panel in accordance with paragraph 34(7), the contractor (or contractors) shall send to the Secretary of State 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 agreement (or agreements); and
 - (c) a brief statement describing the nature and circumstances of the dispute.
- (5) Within the period of 7 days beginning with the date on which the matter was referred to him, the Secretary of State shall—
 - (a) give to the parties notice in writing that he is dealing with the matter; and
 - (b) include with the notice a written request to the parties to make in writing within a specified period any representations which they may wish to make about the dispute.
- (6) The Secretary of State shall give, with the notice given under sub-paragraph (5), to the party other than the one which referred the matter to dispute resolution a copy of any document by which the dispute was referred to dispute resolution.
- (7) The Secretary of State shall, upon receiving any representations from a party, give a copy of them to the other party, and shall in each case request (in writing) a party to which a copy of the

representations is given to make within a specified period any written observations which it wishes to make on those representations.

- (8) For the purpose of assisting it in its consideration of the matter, the Secretary of State may—
- (a) invite representatives of the parties to appear before him 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 he wishes them to give special consideration; or
 - (b) consult other persons whose expertise he considers will assist him in his consideration of the dispute.

(9) Where the Secretary of State consults another person under sub-paragraph (8)(b), he shall notify the parties accordingly in writing and, where he considers that the interests of any party might be substantially affected by the result of the consultation, he shall give to the parties such opportunity as he considers reasonable in the circumstances to make observations on those results.

- (10) In considering the dispute, the Secretary of State shall consider—
- (a) any written representations made in response to a request under sub-paragraph (5)(b), but only if they are made within the specified period;
 - (b) any written observations made in response to a request under sub-paragraph (7), but only if they are made within the specified period;
 - (c) any oral representations made in response to an invitation under sub-paragraph (8)(a);
 - (d) the results of any consultation under sub-paragraph (8)(b); and
 - (e) any observations made in accordance with an opportunity given under sub-paragraph (9).

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

(12) In this paragraph, “specified period” means such period as the Secretary of State shall specify in the request, being not less than one, nor more than two, weeks beginning with the date on which the notice referred to is given, but the Secretary of State may, if the period for determination of the dispute has been extended in accordance with sub-paragraph (16), extend any such period (even after it has expired) and, where he does so, a reference in this paragraph to the specified period is to the period as so extended.

(13) Subject to sub-paragraph (16), within the period of 21 days beginning with the date on which the matter was referred to him, the Secretary of State shall determine whether the Primary Care Trust may assign patients to contractors which have closed their lists of patients; and if he determines that the Primary Care Trust may make such assignments, he shall also determine those contractors to which patients may be assigned.

(14) The Secretary of State may not determine that patients may be assigned to a contractor which was not specified in the determination of the assessment panel under paragraph 34(7).

(15) In the case of a matter referred jointly by contractors in accordance with sub-paragraph (3), the Secretary of State may determine that patients may be assigned to one, some or all of the contractors which referred the matter.

(16) The period of 21 days referred to in sub-paragraph (13) 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 Secretary of State;
- (b) the Primary Care Trust; and
- (c) the contractor (or contractors) which referred the matter to dispute resolution.

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(17) The Secretary of State shall record his determination, and the reasons for it, in writing and shall give notice of the determination (including the record of the reasons) to the parties.

Assignments to closed lists: assignments of patients

36.—(1) Before the Primary Care Trust 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 Primary Care Trust can offer the contractor, and the Primary Care Trust 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

37.—(1) The contractor shall ensure that any prescription form or repeatable prescription for drugs, medicines or appliances issued by a prescriber complies as appropriate with the requirements in paragraphs 38 and 40 to 43.

(2) For the purposes of this paragraph and paragraphs 38 and 40 to 43 in their application to a contractor whose agreement includes the provision of contraceptive services, drugs includes contraceptive substances and appliances includes contraceptive appliances.

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

(2) A prescriber may order drugs, medicines or appliances on a repeatable prescription only where the drugs, medicines or appliances are to be provided more than once.

(3) In issuing any such prescription form or repeatable prescription the prescriber shall himself sign the prescription form or repeatable prescription in ink with his initials, or forenames, and surname in his 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 or repeatable prescription, and—

- (a) the prescription form or repeatable prescription shall not refer to any previous prescription form or repeatable prescription; and
- (b) a separate prescription form or repeatable prescription shall be used for each patient, except where a bulk prescription is issued for a school or institution under paragraph 43.

(4) Where a prescriber orders the drug buprenorphine or a drug specified in Schedule 2 to the Misuse of Drugs Regulations 2001 (controlled drugs to which regulations 14, 15, 16, 18, 19, 20, 21,

23, 26 and 27 of those Regulations apply)(3) for supply by instalments for treating addiction to any drug specified in that Schedule, he shall—

- (a) use only the prescription form provided specially for the purposes of supply by instalments;
- (b) specify the number of instalments to be dispensed and the interval between each instalment; and
- (c) order only such quantity of the drug as will provide treatment for a period not exceeding 14 days.

(5) The prescription form provided specially for the purpose of supply by instalments shall not be used for any purpose other than ordering drugs in accordance with sub-paragraph (4).

(6) In a case of urgency a prescriber may request a chemist to dispense a drug before a prescription form or repeatable prescription 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, other than a drug which is for the time being specified in Schedules 4 or 5 to the Misuse of Drugs Regulations 2001; and
- (c) he undertakes to furnish the chemist, within 72 hours, with a prescription form or repeatable prescription completed in accordance with sub-paragraph (3).

(7) In a case of urgency a prescriber may request a chemist to dispense an appliance before a prescription form or repeatable prescription 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) he undertakes to furnish the chemist, within 72 hours, with a prescription form or repeatable prescription completed in accordance with sub-paragraph (3).

Repeatable prescribing services

39.—(1) The contractor may only provide repeatable prescribing services to any person on its list of patients if it—

- (a) satisfies the conditions in sub-paragraph (2); and
- (b) has notified, in the case where the contractor is other than a Primary Care Trust, the relevant body of its intention to provide repeatable prescribing services in accordance with sub-paragraphs (3) and (4).

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

- (a) except where the contractor is a Primary Care Trust, the contractor holds an agreement with a Primary Care Trust specified in Schedule 9;
- (b) where the contractor is a Primary Care Trust, it is a Primary Care Trust specified in Schedule 9;
- (c) the contractor has access to computer systems and software which enable it to issue repeatable prescriptions and batch issues; and
- (d) the practice premises at which the repeatable prescribing services are to be provided are located in an area of the Primary Care Trust in which there is also located the premises of

(3) S.I.2001/3998.

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at least one chemist who has undertaken to provide, or has entered into an arrangement to provide, repeat dispensing services.

(3) The notification referred to in sub-paragraph (1)(b) is a notification, in writing, by the contractor to the relevant body that it—

- (a) wishes to provide repeatable prescribing services;
- (b) intends to begin to provide those services from a specified date; and
- (c) satisfies the conditions in paragraph (2).

(4) The date specified by the contractor pursuant to sub-paragraph (3)(b) must be at least ten days after the date on which the notification specified in sub-paragraph (1) is given.

(5) Nothing in this paragraph requires a contractor or prescriber to provide repeatable prescribing services to any person.

(6) A prescriber may only provide repeatable prescribing services to a person on a particular occasion if—

- (a) that person has agreed to receive such services on that occasion; and
- (b) the prescriber considers that it is clinically appropriate to provide such services to that person on that occasion.

(7) The contractor may not provide repeatable prescribing services to any patient of its to whom—

- (a) it is authorised or required by the relevant body to provide dispensing services to under paragraphs 46, 48 or 49; or
- (b) any of the persons specified in sub-paragraph (8) is authorised or required by the Primary Care Trust under regulation 20 of the Pharmaceutical Regulations to provide pharmaceutical services.

(8) The persons referred to in sub-paragraph (7) are—

- (a) a medical practitioner who is a party to the agreement;
- (b) in the case of an agreement with a qualifying body, any medical practitioner who is a legal and beneficial shareholder in that body; or
- (c) any medical practitioner employed by the contractor.

Repeatable prescriptions

40.—(1) A prescriber who issues a repeatable prescription must at the same time issue the appropriate number of batch issues.

(2) A prescriber who has provided repeatable prescribing services to a person must, as soon as is practicable, notify that person, and make reasonable efforts to contact the chemist providing repeat dispensing services to that person, if—

- (a) he makes any change to the type, quantity, strength or dosage of drugs, medicines or appliances ordered on that person's repeatable prescription; or
- (b) he considers that it is no longer appropriate or safe for that person to receive the drugs, medicines or appliances ordered on his repeatable prescription, or no longer appropriate or safe for him to continue to receive repeatable prescribing services.

(3) If a prescriber provides repeatable prescribing services to a person in respect of whom he has previously issued a repeatable prescription which has not yet expired (for example, because that person wishes to obtain the drugs, medicines or appliances from a different chemist), the prescriber must make reasonable efforts to notify the chemist which has in its possession the repeatable prescription which is no longer required.

(4) If a prescriber has issued a repeatable prescription in respect of a person, and (before the expiry of that repeatable prescription) it comes to his notice that that person has been removed from the list of patients of the contractor on whose behalf the prescription was issued, that prescriber must—

- (a) notify that person; and
- (b) make reasonable efforts to notify the chemist who has been providing repeat dispensing services to that person,

that the repeatable prescription should no longer be used to obtain or provide repeat dispensing services.

Restrictions on prescribing by medical practitioners

41.—(1) In the course of treating a patient to whom he is providing treatment under the agreement, a medical practitioner shall not order on a prescription form or repeatable prescription a drug, medicine or other substance specified in any directions given by the Secretary of State under section 28U of the Act (GMS contracts: prescription of drugs etc)⁽⁴⁾ as being drugs, medicines or other substances which may not be ordered for patients in the provision of medical services under a general medical services contract but may, subject to regulation 15(2)(b), prescribe such a drug, medicine 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 he is providing treatment under the agreement, a medical practitioner shall not order on a prescription form or repeatable prescription a drug, medicine or other substance specified in any directions given by the Secretary of State under section 28U of the Act as being a drug or medicine 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 or 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 15(2)(b), prescribe such a drug for that patient in the course of that treatment under a private arrangement.

(3) In the course of treating a patient to whom he is providing treatment under the agreement, a medical practitioner shall not order on a prescription form or repeatable prescription 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 15(2)(b), prescribe such an appliance for that patient in the course of that treatment under a private arrangement.

(4) In the course of treating a patient to whom he is providing treatment under the agreement, a medical practitioner shall not order on a repeatable prescription 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 4 or 5 to the Misuse of Drugs Regulations 2001, but may, subject to regulation 15(2)(b), prescribe such a drug for that patient in the course of that treatment under a private arrangement.

Restrictions on prescribing by supplementary prescribers

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

(4) Section 28U was inserted by section 175(1) of the 2003 Act.

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- (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 only under the conditions set out in sub-paragraph (2).

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

- (a) the person satisfies the applicable conditions set out in article 3B(3) of the POM Order (prescribing and administration by supplementary prescribers)⁽⁵⁾, 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 Secretary of State under section 28U 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 a general medical services contract; and
- (d) the drug, medicine or other substance is not specified in any directions given by the Secretary of State under section 28U 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) if the supplementary prescriber is giving a prescription, he 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 he 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—

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

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- (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; and
 - (bb) incidents occurring with the appliance which might lead, might have led or has led to the death or serious deterioration of state of 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) he 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 Secretary of State under section 28U 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 a general medical services 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 Secretary of State under section 28U 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, he 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 sub-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(6); 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 is a prescription for an appliance, the appliance is listed in Part IX 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 IX 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

(6) 1968 c. 67.

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(iii) when giving the prescription, he endorses the face of the form with the reference SLS.

(5) In sub-paragraph (4)(a), “clinical management plan” means a written 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)(7) to implement Directive 2001/83/EC on the Community code relating to medicinal products for human use(8), 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.

Bulk prescribing

43.—(1) Where—

- (a) a contractor is responsible under the agreement for the treatment of 10 or more persons in a school or other institution in which at least 20 persons normally reside; and
- (b) a prescriber orders, for any two or more of those persons for whose treatment the contractor is responsible, drugs, medicines or appliances to which this paragraph applies,

the prescriber may use a single prescription form for the purpose.

(2) Where a prescriber uses a single prescription form for the purpose mentioned in sub-paragraph (1)(b), he shall (instead of entering on the form the names of the persons for whom the drugs, medicines or appliances are ordered) enter on the form—

- (a) the name of the school or institution in which those persons reside; and
- (b) the number of persons residing there for whose treatment the contractor is responsible.

(3) This paragraph applies to any drug, medicine or appliance which can be supplied as part of pharmaceutical services or local pharmaceutical services and which—

- (a) in the case of a drug, is not a product of a description or class which is for the time being specified in an order made under section 58(1) of the Medicines Act 1968 (medicinal products on prescription only)(9); or
- (b) in the case of an appliance, does not contain such a product.

Excessive prescribing

44.—(1) The contractor shall not prescribe drugs and 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 (other than a Primary Care Trust) has breached its obligations under sub-paragraph (1) the relevant body shall seek the views of the Local Medical Committee (if any) for its area.

(7) 1972 c. 68.

(8) OJ L 311, 28.11.2001, p.67.

(9) Section 58(1) was amended by the Medicinal Products: Prescription by Nurses etc Act 1992 (c. 28), section 1 and the 2001 Act, section 63(2).

Dispensing services: general

45. Paragraphs 46 to 48 shall apply to contractors other than Primary Care Trusts and paragraph 49 shall apply to Primary Care Trusts which are contractors.

Provision of dispensing services by contractors other than Primary Care Trusts

46.—(1) Without prejudice to any separate right one or more medical practitioners may have under regulation 20 of the Pharmaceutical Regulations (arrangements for the provision of pharmaceutical services by doctors), a contractor may provide dispensing services to its registered patients under the agreement only if it is authorised or required to do so by the Primary Care Trust in accordance with the following provisions of this paragraph or paragraph 48.

(2) A Primary Care Trust may authorise or require a contractor to provide dispensing services to a registered patient only if that patient—

- (a) satisfies one of the conditions in sub-paragraph (3); and
- (b) has requested the contractor in writing to provide him with dispensing services.

(3) The conditions referred to in sub-paragraph (2)(a) are that the patient—

- (a) satisfies the Primary Care Trust that he would have serious difficulty in obtaining any necessary drugs, medicines or appliances from a pharmacy by reason of distance or inadequacy of means of communication; or
- (b) is resident in a controlled locality at a distance of more than 1.6 kilometres from any pharmacy, and both the conditions in sub-paragraph (4) are satisfied in his case.

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

- (a) the contractor has been granted consent to dispense under paragraph 47 in respect of—
 - (i) the area in which the patient resides, and
 - (ii) the agreement under which the patient receives primary medical services; and
- (b) any conditions imposed in connection with that grant under regulation 12(15) or 13(13) of the Pharmaceutical Regulations as they apply pursuant to paragraph 47(5) or (6) are such as to permit dispensing services to be provided under this paragraph by that contractor to the patient.

(5) If a contractor which has been requested to provide dispensing services by a patient who satisfies one of the conditions in sub-paragraph (3)—

- (a) applies to the Primary Care Trust for the right to provide dispensing services to that patient, and sends with its application the patient's request to the contractor, the Primary Care Trust shall grant its application; or
- (b) does not so apply, within the period of 30 days beginning with the date on which the patient made that request, the Primary Care Trust may, subject to sub-paragraph (7), require the contractor to provide dispensing services to that patient, and shall give the contractor notice in writing to that effect.

(6) An application granted by a Primary Care Trust under sub-paragraph (5)(a) shall, with effect from the date of the patient's request to the contractor, enable that contractor to provide dispensing services to that patient, so long as the agreement remains in effect.

(7) A Primary Care Trust shall not, under sub-paragraph (5)(b), require a contractor to provide dispensing services to a patient if the contractor satisfies the Primary Care Trust that—

- (a) it does not normally provide dispensing services under the agreement; or

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- (b) in the case of a patient to whom sub-paragraph (3)(b) applies, the patient would not have serious difficulty by reason of distance or inadequacy of means of communication in obtaining drugs, medicines or appliances from a pharmacy.
- (8) A Primary Care Trust shall give the contractor reasonable notice—
 - (a) that it requires it to provide dispensing services to a registered patient in accordance with the agreement; or
 - (b) that, subject to sub-paragraph (9), where a patient no longer satisfies the requirements of sub-paragraph (3), the contractor shall discontinue the provision of dispensing services to that patient.
- (9) A notice under sub-paragraph (8)(b)—
 - (a) shall be subject to any postponement or termination of arrangements to provide dispensing services under this paragraph in accordance with conditions imposed under regulation 12(15) or 13(13) of the Pharmaceutical Regulations as they apply pursuant to paragraph 47(5) or (6); and
 - (b) shall not be given—
 - (i) pending the outcome of the resolution of any dispute concerning the decision by a relevant body to postpone the making or termination of arrangements to provide dispensing services under this paragraph in accordance with conditions referred to in paragraph (a), or
 - (ii) during the period for bringing an appeal, or pending the determination of any appeal, referred to in regulation 9(10) of the Pharmaceutical Regulations (determination of whether an area is a controlled locality).
- (10) A contractor which has been granted the right under this paragraph to provide dispensing services to some or all of its registered patients may provide any necessary dispensing services to a person whom that contractor has accepted as a temporary resident.
- (11) In this paragraph, “controlled locality” and “pharmacy” have the same meanings as in the Pharmaceutical Regulations.

Consent to dispense

47.—(1) A contractor which wishes to be granted the right under paragraph 46 to provide dispensing services to its registered patients may apply to the Primary Care Trust in writing for consent to dispense, specifying—

- (a) the area; and
- (b) the agreement,

in relation to which it wishes the consent to dispense to be granted.

(2) An application under sub-paragraph (1) shall be determined by the Primary Care Trust in accordance with regulations 12 and 13 of the Pharmaceutical Regulations (as modified in accordance with sub-paragraphs (5) and (6)), as though it were an application under regulation 21 of those Regulations.

(3) Consent to dispense, in relation to the specified agreement, shall have effect from its final grant but shall cease to have effect if—

- (a) no dispensing services have been provided under that agreement within 12 months from the final grant of the consent to dispense; or
- (b) more than 12 months has elapsed since the last provision of dispensing services under that agreement pursuant to the grant of consent.

(4) In sub-paragraph (3), “final grant” shall be construed in accordance with regulation 12(16) of the Pharmaceutical Regulations.

(5) Regulation 12 of the Pharmaceutical Regulations shall apply as if modified as follows—

- (a) all references to provisions being “subject to regulation 6A” were omitted;
- (b) for all references to regulation 21, there were substituted references to this paragraph;
- (c) in paragraph (14), the reference to “regulation 4(4)” were omitted; and
- (d) in paragraph (15)—
 - (i) for “regulation 20” there were substituted a reference to paragraph 46, and
 - (ii) for the reference to “provision by a doctor of pharmaceutical services” there were substituted a reference to “provision by a contractor of dispensing services”.

(6) Regulation 13 of the Pharmaceutical Regulations shall apply as if modified as follows—

- (a) in paragraph (2), for “regulation 20” there were substituted a reference to paragraph 46; and
- (b) in paragraph (13)(b)—
 - (i) for “regulation 20” there were substituted a reference to paragraph 46, and
 - (ii) for the reference to “provision by a doctor of pharmaceutical services” there were substituted a reference to “provision by a contractor of dispensing services”.

Contractors who previously provided dispensing services under pilot schemes or section 28C arrangements or a general medical services contract

48.—(1) This paragraph applies where, immediately before the commencement of the agreement—

- (a) a medical practitioner who is a party to the agreement, was a pilot doctor in the area of the Primary Care Trust; or
- (b) the contractor was providing primary medical services in the area of the Primary Care Trust under an agreement or a general medical services contract,

and the requirements in sub-paragraph (2) are met.

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

- (a) the pilot doctor, or, as the case may be, the contractor was, immediately before the commencement of the agreement, providing dispensing services to some or all of his or its patients under the pilot scheme or in accordance with an agreement or a general medical services contract; and
- (b) the contractor has notified the Primary Care Trust before entering into the agreement that it intends to provide dispensing services under it.

(3) In a case to which this paragraph applies, the contractor shall be regarded—

- (a) as being authorised or required under paragraph 46 to provide dispensing services under the agreement to any patient—
 - (i) to whom, immediately before commencement of the agreement, it or, as the case may be, the pilot doctor, provided dispensing services under the pilot scheme, agreement or general medical services contract, and
 - (ii) who wishes the contractor to continue to provide him with such services; and
- (b) subject to sub-paragraph (5), as having been granted consent to dispense in relation to the agreement under paragraph 47 in relation to the area for which it or, as the case may be,

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the pilot doctor, had such consent under the pilot scheme, agreement or general medical services contract.

(4) Paragraph 47(3) shall apply in relation to an agreement to which this paragraph applies as if the references to the final grant of the consent to dispense were references to the date of commencement of the agreement.

(5) In this paragraph “pilot doctor” means a medical practitioner who performs personal medical services in connection with a pilot scheme and “pilot scheme” means an agreement made under Part 1 of the National Health Service (Primary Care) Act 1997(10).

Provision of dispensing services by Primary Care Trusts

49.—(1) A Primary Care Trust may provide dispensing services under the agreement to its registered patients with the consent of the Strategic Health Authority.

(2) A Primary Care Trust may provide dispensing services to a registered patient only if that patient—

- (a) satisfies one of the conditions in sub-paragraph (3); and
 - (b) has requested the Primary Care Trust in writing to provide him with dispensing services.
- (3) The conditions referred to in sub-paragraph (2)(a) are that the patient—
- (a) satisfies the Primary Care Trust that he would have serious difficulty in obtaining any necessary drugs, medicines or appliances from a pharmacy by reason of distance or inadequacy of means of communication; or
 - (b) is resident in a controlled locality at a distance of more than 1.6 kilometres from any pharmacy.

(4) A Primary Care Trust which provides dispensing services to some or all of its registered patients may provide any necessary dispensing services to a person whom it has accepted as a temporary resident.

(5) In this paragraph, “controlled locality” and “pharmacy” have the same meanings as in the Pharmaceutical Regulations.

Terms relating to the provision of dispensing services

50.—(1) A contractor which has been granted the right to provide dispensing services under paragraph 46, 48 or 49 shall ensure that dispensing services are provided in accordance with the following sub-paragraphs.

- (2) Subject to sub-paragraphs (3) and (4), a contractor providing dispensing services shall—
- (a) record an order for the provision of any drugs, medicines or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with paragraph 38(3);
 - (b) provide those drugs, medicines or appliances in a suitable container;
 - (c) provide for the patient a drug or medicine specified in any directions given by the Secretary of State under section 28U of the Act as being a drug or medicine which can only be ordered for specified patients and specified purposes only if—
 - (i) that patient is a person of the specified description, and
 - (ii) the drug or medicine is supplied for that patient only for the specified purpose; and
 - (d) provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

(10) 1997 c. 46.

(3) Sub-paragraph (2) does not apply to drugs, medicines or appliances ordered on a prescription form by an independent nurse prescriber.

(4) Where a patient presents an order on a prescription form for drugs, medicines or appliances signed by an independent nurse prescriber, or an order for a restricted availability appliance signed by and endorsed on its face with the reference “SLS” by an independent nurse prescriber, to a medical practitioner who may provide dispensing services, the contractor may provide to the patient such of the drugs, medicines or appliances so ordered as it supplies in the normal course of providing services under the agreement.

(5) Drugs, medicines or appliances provided under sub-paragraph (4) shall be provided in a suitable container.

(6) A contractor providing dispensing services shall not provide for a patient a drug or medicine specified in any directions given by the Secretary of State under section 28U of the Act as being drugs or medicines which may not be ordered for patients in the provision of medical services under the general medical services contract, except that, where it has ordered a drug or medicine which has an appropriate non-proprietary name either by the name or by its formula, it may provide a drug or medicine which has the same specification notwithstanding that it is a drug or medicine specified in such directions (but, in the case of a drug or medicine which combines more than one drug, only if the combination has an appropriate non-proprietary name).

(7) Subject to sub-paragraph (9), nothing in this paragraph shall prevent a medical practitioner providing a Scheduled drug or a restricted availability appliance in the course of treating a patient under a private arrangement.

(8) A contractor providing dispensing services shall comply with paragraph 11B of Schedule 2 to the Pharmaceutical Regulations(11), as if modified as follows—

- (a) for “paragraph 11(a)”, substitute “sub-paragraph (3)(a)”;
- (b) for “paragraph 11A(2)”, substitute “sub-paragraph (5)”;
- (c) for “a doctor who is authorised or required by the Health Authority or Primary Care Trust under regulation 20 to provide drugs and appliances to a patient”, substitute “a contractor providing dispensing services to a patient”; and
- (d) for “doctor”, substitute “contractor”.

(9) The provisions of regulation 15 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.

(10) A contractor which is entitled to provide dispensing services may, with the consent of the patient, order a drug, medicine or appliance for a patient on a prescription form or a repeatable prescription, rather than providing it itself.

Dispensing contractor list

51.—(1) Where the contractor is authorised or required by the relevant body under paragraph 46 or 48 to provide dispensing services to its patients and is actually doing so, the Primary Care Trust in whose area most of the contractor’s patients reside shall include—

- (a) the contractor’s name;
- (b) the address of the contractor’s premises from which it is authorised or required to dispense; and
- (c) that the contractor is a contractor providing services under an agreement,

(11) Paragraph 11B was inserted by S.I. 1999/696 and amended by S.I. 1999/2563, 2001/2888, 2002/551 and 2469 and 2003/699 and 1084.

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in its dispensing contractors list which it prepares and maintains under paragraph 51 of Schedule 6 to the General Medical Services Contracts Regulations (dispensing contractor list).

(2) The Primary Care Trust shall remove the name of the contractor from the list referred to in sub-paragraph (1) where—

- (a) the contractor's consent to dispense ceases to have effect pursuant to paragraph 47(3); or
- (b) the contractor ceases to provide dispensing services to its patients for any other reason.

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

52.—(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 he 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⁽¹²⁾ or any regulations or orders made thereunder.

PART 4

PERSONS WHO PERFORM SERVICES

Qualifications of performers

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

- (a) included in a medical performers list of a Primary Care Trust in England;
- (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)⁽¹³⁾.

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

- (a) a medical practitioner employed by (in England and Wales and Scotland) an NHS trust, an NHS foundation trust, (in Scotland) a Health Board, or (in Northern Ireland) 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⁽¹⁴⁾ acting in the course of his employment in a resident medical capacity in an approved medical practice; or
- (c) a GP Registrar during the first two months of his training period.

⁽¹²⁾ 1968 c. 67.

⁽¹³⁾ 1983 c. 54. Section 41A was inserted by S.I. 2000/1803.

⁽¹⁴⁾ Section 15A was inserted by regulations 2 and 3 of S.I. 2000/3041 and section 21 was amended by S.I. 2002/3135.

54. No health care professional other than one to whom paragraph 53 applies shall perform clinical services under the agreement unless he is appropriately registered with his relevant professional body and his registration is not currently suspended.

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

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

Conditions for employment and engagement

57.—(1) Subject to sub-paragraphs (2) and (3), a contractor shall not employ or engage a medical practitioner (other than one falling within paragraph 53(2)) unless—

- (a) that practitioner has provided it with the name and address of the Primary Care Trust on whose primary medical performers list he appears; and
- (b) the contractor has checked that the practitioner meets the requirements in paragraph 53.

(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 53 in accordance with sub-paragraph (1)(b) before employing or engaging him he may be employed or engaged on a temporary basis for a single period of up to seven 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 Primary Care Trust on whose list he has applied for inclusion; and
- (b) confirmation that his name appears on that list shall not be required until the end of the first two months of the Registrar's training period.

58.—(1) The contractor shall not employ or engage—

- (a) a health care professional other than one to whom paragraph 53 applies unless the contractor has checked that he meets the requirements in paragraph 54; or
- (b) a health care professional to perform clinical services unless he has taken reasonable steps to satisfy himself that he meets the requirements in paragraph 56.

(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 54 in accordance with sub-paragraph (1) before employing or engaging him, he may be employed or engaged on a temporary basis for a single period of up to seven 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 him and any relevant clinical experience gained by him.

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

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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 health care professional 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 him, he may be employed or engaged on a temporary basis for a single period of up to fourteen days whilst his references are checked and considered, and for an additional single period of a further seven 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.

60.—(1) Before employing or engaging any person to assist it in the provision of services under the agreement, 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 he is to be employed or engaged.

(2) The duty imposed by sub-paragraph (1) is in addition to the duties imposed by paragraphs 57 to 59.

(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) his education and training; and
- (c) his previous employment or work experience.

Training

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

- (a) performing clinical services under the agreement; 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 his skills and knowledge in relation to the services which he is performing or assisting in performing.

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

Arrangements for GP Registrars

63.—(1) The contractor shall only employ a GP Registrar for the purpose of being trained by a GP Trainer 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 agreement or for which other staff assist them in the performance of those services.

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

- (a) offer him terms of employment in accordance with the rates and subject to the conditions contained in any directions given by the Secretary of State to Strategic Health Authorities

under section 17 of the Act (Secretary of State's directions: exercise of functions)(15) concerning the grants, fees, travelling and other allowances payable to GP Registrars(16); and

- (b) take into account any guidance issued by the Secretary of State in relation to the GP Registrar Scheme(17).

Doctors with provisional registration

64. A contractor shall not by reason only of having employed or engaged a person who is provisionally registered under section 15, 15A or 21 of the Medical Act and is acting in the course of his employment in a resident medical capacity in an approved medical practice, reduce the total number of hours in which other staff assist in the performance of medical services under the agreement.

Independent nurse prescribers and supplementary prescribers

65.—(1) This paragraph applies to contractors other than Primary Care Trusts.

(2) 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 party to the agreement is an independent nurse prescriber or a supplementary prescriber whose functions will include prescribing unless immediately before becoming such a party, he fell within paragraph (a); or
- (c) the functions of a person who is an independent nurse prescriber or a supplementary prescriber are extended to include prescribing,

it shall notify the relevant body in writing within the period of seven days beginning with the date on which it employed or engaged the person, the party became a party to the agreement or the person's functions were extended, as the case may be.

(3) 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;
- (b) the party to the agreement who is an independent nurse prescriber or a supplementary prescriber whose functions included prescribing, ceases to be a party to the agreement;
- (c) the functions of a person who is an independent nurse prescriber or a supplementary prescriber are changed so that they no longer include prescribing in its practice; or
- (d) the contractor becomes aware that an independent nurse prescriber or a supplementary prescriber has been removed or suspended from the relevant register,

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

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

- (a) the person's full name;

(15) Section 17 was amended by the 2001 Act, section 67(1) and Schedule 5, paragraph 5(1) and (3) and the 2002 Act, section 1(3) and Schedule 1, paragraph 7.

(16) The current directions are the Directions to Strategic Health Authorities concerning GP Registrars dated 3rd November 2003. A copy of these directions can be obtained by writing to the Department of Health, P.O. Box 777, London SE1 6XH.

(17) 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 its website at www.doh.gov.uk/medicaltrainingintheuk or by writing to the Department of Health, P.O. Box 777, London SE1 6XH.

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- (b) his professional qualifications;
 - (c) his identifying number which appears in the relevant register;
 - (d) the date on which his entry in the relevant register was annotated to the effect that he was qualified to order drugs, medicines and appliances for patients;
 - (e) the date on which—
 - (i) he was employed or engaged, if applicable,
 - (ii) he became a party to the agreement, if applicable, or
 - (iii) one of his functions became to prescribe.
- (5) The contractor shall provide the following information when it notifies the relevant body in accordance with sub-paragraph (3)—
- (a) the person's full name;
 - (b) his professional qualifications;
 - (c) his identifying number which appears in the relevant register; and
 - (d) the date—
 - (i) he ceased to be employed or engaged in its practice,
 - (ii) he ceased to be a party to the agreement,
 - (iii) his functions changed so as no longer to include prescribing, or
 - (iv) on which he was removed or suspended from the relevant register.

Signing of documents

66.—(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 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—
- (a) certificates issued in accordance with regulation 12, unless regulations relating to particular certificates provide otherwise;
 - (b) prescription forms and repeatable prescriptions; and
 - (c) any other clinical documents.

Level of skill

67. The contractor shall carry out its obligations under the agreement with reasonable care and skill.

Appraisal and assessment

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

- (a) participates in the appraisal system provided by the relevant body or where the contractor is a Primary Care Trust, by it, unless he participates in an appropriate appraisal system provided by another health service body or is an armed forces GP; and
- (b) co-operates with an assessment by the NCAA when requested to do so by the relevant body or where the contractor is a Primary Care Trust, by it.

(2) The relevant body which is a Primary Care Trust shall provide an appraisal system for the purposes of sub-paragraph (1) (a).

Sub-contracting of clinical matters

69.—(1) The contractor shall not sub-contract any of its rights or duties under the agreement in relation to clinical matters unless it has taken reasonable steps to satisfy itself that—

- (a) it is reasonable in all the circumstances;
- (b) that the person is qualified and competent to provide the service; and
- (c) it is satisfied in accordance with paragraph 113 that the sub-contractor holds adequate insurance.

(2) Where the contractor sub-contracts any of its rights or duties under the agreement in relation to clinical matters, it shall—

- (a) inform the relevant body of the sub-contract as soon as is reasonably practicable; and
- (b) provide the relevant body with such information in relation to the sub-contract as it reasonably requests.

(3) Where the contractor sub-contracts clinical services under sub-paragraph (1), the parties to the agreement shall be deemed to have agreed a variation to the agreement which has the effect of adding to the list of the contractor's premises any premises which are to be used by the sub-contractor for the purpose of the sub-contract and paragraph 98(1) shall not apply.

(4) A contractor must ensure that any person with whom it sub-contracts is prohibited from sub-contracting the clinical services it has agreed with the contractor to provide.

PART 5

RECORDS, INFORMATION, NOTIFICATIONS AND RIGHTS OF ENTRY

Patient records

70.—(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 patients.

(3) A contractor which provides essential services (other than a Primary Care Trust) shall keep the records referred to in sub-paragraph (2)—

- (a) on forms supplied to it for the purpose by the relevant body; or
- (b) with the written consent of the relevant body, by way of computerised records,

or in a combination of those two ways.

(4) A contractor which provides essential services shall include in the records referred to in sub-paragraph (2) clinical reports sent in accordance with paragraph 5 of this Schedule or from any other health care professional who has provided clinical services to a person on its list of patients.

(5) The consent of the relevant body required by sub-paragraph (3)(b) shall not be withheld or withdrawn provided the relevant body 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 Secretary of State or another person on his behalf in accordance

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with “General Medical Practice Computer Systems—Requirements for Accreditation—RFA99” version 1.0, 1.1 or 1.2 (DTS/Nurse Prescribing)(18);

- (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 the guidelines contained in “Good Practice Guidelines for General Practice Electronic Patient Records” published on 26th September 2003(19).

(6) Where a patient’s records are computerised records, the contractor (other than the Primary Care Trust) shall, as soon as possible following a request from the relevant body, allow the relevant body to access the information recorded on the computer system on which those records are held by means of the audit function referred to in sub-paragraph (5)(b) to the extent necessary for the relevant body to confirm that the audit function is enabled and functioning correctly.

(7) The contractor (other than a Primary Care Trust) shall send the complete records relating to a patient to the relevant body—

- (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 relevant body 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 as soon as possible, at the request of the relevant body; 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 relevant body.

(8) To the extent that a patient’s records are computerised records, the contractor complies with sub-paragraph (7) if it sends to the relevant body a copy of those records—

- (a) in written form; or
- (b) with the written consent of the relevant body in any other form.

(9) The consent of the relevant body to the transmission of information other than in written form for the purposes of sub-paragraph (8)(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 relevant body is identical to that transmitted; and
- (d) how a written copy of the record can be produced by the relevant body.

(10) A contractor whose patient’s 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 (5)(b).

Confidentiality of personal data

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

(18) RFA99 is published by the NHS Information Authority. Version 1.0 was published in October 1999; version 1.1 in February 2001; and version 1.2 (DTS/Nurse Prescribing) in August 2003. Copies are available on the NHS Information Authority’s website at www.nhs.uk/nhsia/sat/specification/pages. Copies may also be obtained by writing to the NHS Information Authority, Systems Accreditation and Testing team, Aqueous 2, Aston Cross, Rocky Lane, Birmingham B6 5RQ.

(19) This document is available on the Department of Health website at www.doh.gov.uk/pricare/computing or a copy can be obtained by writing to the Department of Health, PCIT Branch, Room 1N06, Quarry House, Quarry Hill, Leeds LS2 7UE.

Contractor's leaflet

72. A contractor which provides essential services shall—
- (a) compile a document (in this paragraph called a practice leaflet) which shall include the information specified in Schedule 10;
 - (b) review its practice leaflet at least once in every period of 12 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

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

- (a) any information which is reasonably required by the relevant body for the purposes of or in connection with the agreement; and
- (b) except where the contractor is a Primary Care Trust, any other information which is reasonably required by it in connection with the relevant body'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 relevant body in accordance with directions made by the Secretary of State under section 17 of the Act (Secretary of State's directions: exercise of functions)(20).

Requests for information from Patients' Forums

74.—(1) Subject to sub-paragraph (2), where the contractor (other than a Primary Care Trust) receives a written request from the Patients' Forum established for the relevant body to produce any information which appears to the Forum to be necessary for the effective carrying out of its functions it shall comply with that request promptly and in any event no later than the twentieth working day following the date the request was made.

- (2) The contractor shall not be required to produce information under sub-paragraph (1) which—
- (a) is confidential and relates to a living individual, unless at least one of the conditions specified in sub-paragraph (3) applies; or
 - (b) is prohibited from disclosure by or under any enactment or any ruling of a court of competent jurisdiction or is protected by the common law, unless sub-paragraph (4) applies.
- (3) The conditions referred to in sub-paragraph (2)(a) are—
- (a) the information can be disclosed in a form from which the identity of the individual cannot be ascertained; or
 - (b) the individual consents to the information being disclosed.
- (4) This paragraph applies where—
- (a) the prohibition of the disclosure of information arises because the information is capable of identifying an individual; and
 - (b) the information can be disclosed in a form from which the identity of the individual cannot be ascertained.

(20) Section 17 of the Act was substituted by the Health Act 1999 (c. 8), section 12(1) and amended by the 2001 Act, Schedule 5, paragraph 5(3) and the 2002 Act, section 1(3) and Schedule 1, paragraph 7.

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- (5) In a case where the information falls within—
- (a) sub-paragraph (2)(a) and the condition in sub-paragraph (3)(a) applies; or
 - (b) sub-paragraph (2)(b) and sub-paragraph (4) applies,

a Patients' Forum may require the contractor to disclose the information in a form from which the identity of the individual concerned cannot be ascertained.

Inquiries about prescriptions and referrals

75.—(1) A contractor (other than a Primary Care Trust) shall, subject to sub-paragraphs (2) and (3), sufficiently answer any inquiries whether oral or in writing from the relevant body concerning—

- (a) any prescription form or repeatable prescription 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 relevant body to discharge its functions or of assisting the contractor in the discharge of its obligations under the agreement.

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

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

Reports to a medical officer

76.—(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 his behalf and at his direction, may specify, such clinical information as the medical officer considers relevant about a patient to whom the contractor or a person acting on the contractor's 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 for Work and Pensions on his behalf and at his 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 the contractor's behalf has made in a report.

(2) For the purpose of satisfying himself 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 he holds the patient's written consent.

Annual return and review

77.—(1) The contractor shall submit an annual return relating to the agreement to the relevant body which shall require the same categories of information from all persons who hold agreements with that body.

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

(3) The relevant body 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.

(4) A copy of the final record referred to in sub-paragraph (3) shall be sent to the contractor.

Notifications to the relevant body

78. In addition to any requirements of notification elsewhere in the regulations, the contractor shall notify the relevant body 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 agreement;
- (b) any circumstances which give rise to the relevant body's right to terminate the agreement under paragraph 103, 104 or 105;
- (c) except where the contractor is a Primary Care Trust, any appointments system which it proposes to operate and the proposed discontinuance of any such system;
- (d) except where the contractor is a Primary Care Trust, 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.

79. The contractor (other than a Primary Care Trust) shall, unless it is impracticable for it to do so, notify the relevant body in writing within 28 days of any occurrence requiring a change in the information about it published by the relevant body in accordance with regulations made under section 16CC(3) of the Act (primary medical services)(21).

Notice provisions specific to an agreement with a qualifying body

80.—(1) Where a qualifying body is a party to the agreement, the contractor shall give notice in writing to the relevant body forthwith when—

- (a) any share in the qualifying body is transmitted or transferred (whether legally or beneficially) to another person on a date after the agreement has been entered into;
- (b) the qualifying body passes a resolution or a court of competent jurisdiction makes an order that the qualifying body be wound up;
- (c) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the qualifying body;
- (d) circumstances arise which would enable the court to make a winding up order in respect of the qualifying body; or
- (e) the qualifying body is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 (definition of inability to pay debts)(22).

(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—

(21) Section 16CC was inserted into the Act by section 170 of the 2003 Act.

(22) 1986 c. 45.

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- (a) falls within section 28D(1)(a), (b), (ba), (bb), (bc), (d) and (f) of the Act (persons with whom agreements may be made)(**23**); and
- (b) meets the further conditions imposed on shareholders by virtue of regulations 4 and 5.

Notification of deaths

81.—(1) The contractor shall report in writing to the relevant body the death on the contractor's 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 contractor's premises; and
- (f) the name, where known, of any other person who was present at the time of the death.

(3) The contractor shall send a copy of the report referred to in sub-paragraph (1) to any other Primary Care Trust in whose area the deceased was resident at the time of his death.

(4) The contractor shall also send a copy of the report referred to in sub-paragraph (1) to any other relevant body with whom it has an agreement to provide primary medical services.

Notifications to patients following variation of the agreement

82. Where the agreement 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 relevant body, or where the relevant body is a Strategic Health Authority, the contractor, 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 relevant body

83.—(1) Subject to the conditions in sub-paragraph (2), the contractor shall allow persons authorised in writing by the relevant body to enter and inspect its 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.

(23) Section 28D was inserted by section 21(1) of the 1997 Act and was amended by the 1999 Act, section 65(1), Schedule 4, paragraphs 4 and 16a; the 2002 Act, section 4(3), Schedule 3, paragraph 7(3) and the 2003 Act, section 177(1) to (6) and section 184 and Schedule 11, paragraph 15.

Entry and inspection by members of Patients' Forums

84. The contractor (other than a Primary Care Trust) shall allow members of a Patients' Forum authorised by or under regulation 3 of the Patients' Forums (Functions) Regulations 2003 to enter and inspect the practice premises for the purpose of any of the Forum's functions in accordance with the requirements of that regulation.

Entry and inspection by the Commission for Healthcare Audit and Inspection

85. The contractor (other than a Primary Care Trust) shall allow persons authorised by the Commission for Healthcare Audit and Inspection to enter and inspect the premises in accordance with section 66 of the Health and Social Care (Community Health and Standards) Act 2003 (right of entry)(23).

PART 6

COMPLAINTS

Complaints procedure

86.—(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 agreement.

(2) The complaints procedure required by sub-paragraph (1) shall—

(a) until the coming into force of regulations in relation to complaints about primary medical services provided under section 28C arrangements made under section 113 of the Health and Social Care (Community Health and Standards) Act 2003 (complaints about health care)(24) comply—

(i) where the contractor is not a Primary Care Trust, with the requirements in paragraphs 87 to 90, or

(ii) where the contractor is a Primary Care Trust with any directions made under section 17 of the Act; and

(b) on the coming into force of such regulations, comply with those regulations.

(3) The contractor shall take reasonable steps to ensure that—

(a) the complaints procedure is accessible to all patients; and

(b) patients are aware of—

(i) the name of the person responsible for the operation of the contractor's complaints procedure,

(ii) the complaints procedure,

(iii) the role of the relevant body (except where the contractor is a Primary Care Trust) and other bodies in relation to complaints about services under the agreement, and

(iv) their right to assistance with any complaint from independent advocacy services provided under section 19A of the Act (independent advocacy services)(25).

(23) Section 28D was inserted by section 21(1) of the 1997 Act and was amended by the 1999 Act, section 65(1), Schedule 4, paragraphs 4 and 16a; the 2002 Act, section 4(3), Schedule 3, paragraph 7(3) and the 2003 Act, section 177(1) to (6) and section 184 and Schedule 11, paragraph 15.

(24) 2003 c. 43.

(25) Section 19A was inserted by the Health and Social Care Act 2001 (c. 15), section 12.

Making of complaints

87. A complaint may be made by or, with his consent, on behalf of a patient, or former patient, who is receiving or has received services under the agreement, or—

- (a) where the 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 a local authority to whose care the child has been committed under the provisions of the Children Act 1989⁽²⁶⁾, 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) where the patient is incapable of making a complaint, by a relative or other adult who has an interest in his welfare.

88. Where a patient has died a complaint may be made by a relative or other adult who had an interest in his welfare or, where the patient falls within paragraph 87(a)(ii) or (iii), by the authority or voluntary organisation.

Period for making complaints

89.—(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 12 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 referred to in paragraph 90(2)(a) and if he 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

90.—(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 his job title) to be responsible for the operation of the complaints procedure and the investigation of complaints; and
- (b) an individual who is a party to the agreement or other 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.

(26) 1989 c. 41.

- (3) All complaints must be—
- (a) either made or recorded in writing;
 - (b) acknowledged in writing within the period of three 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) 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) must inform the patient or person acting on his 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

91.—(1) The contractor (other than a Primary Care Trust) shall co-operate with any investigation of a complaint in relation to any matter reasonably connected with the provision of services by the contractor undertaken by—

- (a) the relevant body in accordance with directions given under section 17 of the Act; and
- (b) the Commission for Healthcare Audit and Inspection.

(2) The contractor shall co-operate with any investigation of a complaint by an NHS body or local authority which relates to a patient or former patient of the contractor.

(3) In sub-paragraph (2)—

“NHS body” means a Primary Care Trust, (in England and Wales and Scotland) an NHS trust, an NHS foundation trust, a Strategic Health Authority, a Local Health Board, a Health Board, a Health and Social Services Board or a Health and Social Services Trust;

“local authority” means—

- (a) any of the bodies listed in section 1 of the Local Authority Social Services Act 1970 (local authorities)(**27**);
- (b) the Council of the Isles of Scilly; or
- (c) a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 (constitution of councils)(**28**).

(4) The co-operation required by sub-paragraphs (1) and (2) includes—

- (a) answering questions reasonably put to the contractor by the relevant body;
- (b) providing any information relating to the complaint reasonably required by the relevant body; 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 relevant body.

(27) 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.

(28) 1994 c. 39.

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Provision of information about complaints

92. The contractor (other than a Primary Care Trust) shall inform the relevant body, at such intervals as required, of the number of complaints that it has received under the procedure established in accordance with this Part.

PART 7

DISPUTE RESOLUTION

Local resolution of agreement disputes

93.—(1) Subject to sub-paragraph (2), in the case of any dispute arising out of or in connection with the agreement, the contractor and the relevant body must make every reasonable effort to communicate and cooperate 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) In the case of a dispute which falls to be dealt with under the procedure specified in paragraph 35, 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 35(4).

Dispute resolution: non-NHS contracts

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

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

(2) In the case of a dispute referred to the Secretary of State 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

95.—(1) Subject to sub-paragraph (2), the procedure specified in the following sub-paragraphs and paragraph 96 applies in the case of any dispute arising out of or in connection with the agreement which is referred to the Secretary of State—

- (a) in accordance with section 4(3) of the 1990 Act (where the agreement is an NHS contract); or
- (b) in accordance with paragraph 94(1) (where the agreement is not an NHS contract).

(2) The procedure specified in this paragraph and paragraph 96 does not apply where a contractor refers a matter for determination in accordance with paragraph 35(1) of this Schedule, and in such a case the procedure specified in that paragraph shall apply instead.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) shall send to the Secretary of State 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 agreement; 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 three 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) Where the dispute relates to an agreement which is not an NHS contract, the Secretary of State may determine the matter himself or, if he considers it appropriate, appoint a person or persons to consider and determine it(29).
- (6) Before reaching a decision as to who should determine the dispute, either under sub-paragraph (5) or under section 4(5) of the 1990 Act, the Secretary of State shall, within the period of 7 days beginning with the date on which a matter was referred to him, 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 Secretary of State shall give, 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 Secretary of State 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 Secretary of State shall, if he decides to appoint a person or persons to hear the dispute—
- (a) inform the parties in writing of the name of the person or persons whom he has appointed; and
 - (b) pass to the person or persons so appointed any documents received from the parties under or pursuant to sub-paragraph (3), (6) or (8).
- (10) For the purpose of assisting him in his consideration of the matter, the adjudicator may—
- (a) invite representatives of the parties to appear before him 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 he wishes them to give special consideration; or
 - (b) consult other persons whose expertise he considers will assist him in his consideration of the matter.
- (11) Where the adjudicator consults another person under sub-paragraph (10)(b), he shall notify the parties accordingly in writing and, where he considers that the interests of any party might be substantially affected by the result of the consultation, he shall give to the parties such opportunity as he 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

(29) Where the dispute relates to an agreement which is an NHS contract, section 4(5) of the 1990 Act applies.

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(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 Secretary of State shall specify in the request, being not less than two, nor more than four, weeks beginning with the date on which the notice referred to is given, but the Secretary of State may, if he considers that there is good reason for doing so, extend any such period (even after it has expired) and, where he 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 96 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.

Determination of dispute

96.—(1) The adjudicator shall record his determination and the reasons for it in writing and shall give notice of the determination (including the record of the reasons) to the parties.

(2) Where the adjudicator makes a direction as to payments under section 4(7) of the 1990 Act (as it has effect as a result of regulation 9 or paragraph 94(1)), that direction is to be enforceable in a county court (if the court so orders) as if it were a judgment or order of that court.

(3) In the case of an agreement referred for determination in accordance with paragraph 94(1), subsection (8) of section 4 of the 1990 Act shall apply as that subsection applies in the case of an agreement referred for determination in accordance with subsection (3) of section 4 of that Act.

Interpretation of Part 7

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

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

PART 8

VARIATION AND TERMINATION OF AGREEMENTS

Variation of an agreement: general

98.—(1) Subject to sub-paragraph (2) and paragraphs 70(3) and 109, no amendment or variation shall have effect unless it is in writing and signed by or on behalf of the relevant body and the contractor.

(2) In addition to the specific provision made in paragraph 109, the relevant body may vary the agreement without the contractor’s consent where it—

- (a) is reasonably satisfied that it is necessary to vary the agreement so as to comply with the Act, any regulations made pursuant to that Act, or any direction given by the Secretary of State 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.

Termination by agreement

99. The relevant body and the contractor may agree in writing to terminate the agreement, 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 agreement should be terminated.

Termination by notice

100.—(1) Either the contractor or the relevant body may terminate the agreement by serving notice in writing on the other party.

(2) Where a notice is served pursuant to sub-paragraph (1), the agreement shall terminate on the date provided for under the agreement.

Late payment notices

101.—(1) The contractor may give notice in writing (a “late payment notice”) to the relevant body if the relevant body has failed to make any payments due to the contractor in accordance with a term of the agreement that has the effect specified in regulation 12, and the contractor shall specify in the late payment notice the payments that the relevant body 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 agreement by a further written notice if the relevant body has still failed to make the payments due to the contractor, and that were specified in the late payment notice served on the relevant body pursuant to sub-paragraph (1).

(3) If, following receipt of a late payment notice, the relevant body 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 agreement pursuant to sub-paragraph (2) until—

- (a) there has been a determination of the dispute pursuant to paragraph 95 and that determination permits the contractor to terminate the agreement; or
- (b) the relevant body ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(4) Paragraph 100 and sub-paragraphs (1), (2) and (3) are without prejudice to any other rights to terminate the agreement that the contractor may have.

Termination by the relevant body: general provisions

102. The relevant body may only terminate the agreement in accordance with the provisions in this Part.

Termination by the relevant body for breach of conditions in regulation 4

103. The relevant body shall serve notice in writing on the contractor terminating the agreement forthwith if—

- (a) a medical practitioner who is a party to the agreement no longer satisfies the condition specified in regulation 4(1); or
- (b) a qualifying body which is a party to the agreement no longer satisfies the condition specified in regulation 4(2).

Termination by the relevant body for the provision of untrue etc information

104. The relevant body may serve notice in writing on the contractor terminating the agreement forthwith, or from such date as may be specified in the notice if, after the agreement has been entered into, it comes to the attention of the relevant body that written information provided to the relevant body by the contractor before the agreement 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.

Termination by the relevant body on fitness grounds

105.—(1) The relevant body may serve notice in writing on the contractor terminating the agreement forthwith, or from such date as may be specified in the notice if—

- (a) in the case of an agreement with an individual as a party, that individual; or
- (b) in the case of an agreement with a qualifying body as a party—
 - (i) the qualifying body,
 - (ii) any person legally and beneficially owning a share in the qualifying body, or
 - (iii) any director or secretary of the qualifying body,

falls within sub-paragraph (3) during the existence of the agreement.

(2) In the case of a person who is a party to an agreement made before the 1st April 2004 and which is deemed to be an agreement made under section 28C of the Act, the reference to “during the existence of the agreement” shall be read as excluding any period before the 1st April 2004.

(3) A person falls within this sub-paragraph if—

- (a) he or it (in the case of a qualifying body) is the subject of a national disqualification;
- (b) subject to sub-paragraph (4), he or it 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;
- (c) subject to sub-paragraph (5), he has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless before the relevant body has served a notice terminating the agreement pursuant to this paragraph, he is employed by the health service body that dismissed him or by another health service body;
- (d) he or it is removed from, or refused admission to, a primary care list by reason of inefficiency, fraud or unsuitability (within the meaning of section 49F(2), (3) and (4) respectively⁽³⁰⁾) unless his name has subsequently been included in such a list;
- (e) he has been convicted in the United Kingdom of murder;
- (f) he has been convicted in the United Kingdom of a criminal offence and has been sentenced to a term of imprisonment of over six months;
- (g) subject to sub-paragraph (6), he has been convicted elsewhere of an offence—
 - (i) which would, if committed in England and Wales, constitute murder, or
 - (ii) which would, if committed in England and Wales, constitute a criminal offence other than murder, and been sentenced to a term of imprisonment of over six months;
- (h) he has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933⁽³¹⁾;

⁽³⁰⁾ Section 49F was inserted into the Act by section 25 of the 2001 Act and amended by the 2002 Act, section 2(5) and Schedule 2, paragraph 21 and by the 2003 Act, Schedule 14.

⁽³¹⁾ 1933 c. 12 as amended by the Criminal Justice Act 1988 (c. 33), section 170, Schedule 15, paragraph 8 and Schedule 16, paragraph 16; 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.

- (i) he or it has—
 - (i) been adjudged bankrupt or had sequestration of his estate awarded unless (in either case) he 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⁽³²⁾, 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, his or its creditors unless he or it has been discharged in respect of it,
 - (iv) an administrator, administrative receiver or receiver appointed in respect of it,
 - (v) an administration order made in respect of it under Schedule B1 to the Insolvency Act 1986⁽³³⁾, or
 - (vi) been wound up under Part IV of the Insolvency Act 1986;
 - (j) he has been—
 - (i) 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 he was responsible or to which he was privy, or which he by his conduct contributed to or facilitated, or
 - (ii) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990 (powers of the Court of Session to deal with management of charities)⁽³⁴⁾, from being concerned in the management or control of any body;
 - (k) he is subject to a disqualification order under the Company Directors Disqualification Act 1986⁽³⁵⁾, the Companies (Northern Ireland) Order 1986⁽³⁶⁾ or to an order made under section 429(2)(b) of the Insolvency Act 1986 (failure to pay under county court administration order)⁽³⁷⁾; or
 - (l) has refused to comply with a request by the relevant body for him to be medically examined on the grounds that it is concerned that he is incapable of adequately providing services under the agreement.
- (4) A relevant body shall not terminate the agreement pursuant to sub-paragraph (3)(b) where the relevant body 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 party to the agreement;
 - (b) in the case of an agreement with a qualifying body—
 - (i) a person legally and beneficially owning a share in the qualifying body, or
 - (ii) a director or secretary of the qualifying body,as the case may be.
- (5) A relevant body shall not terminate the agreement pursuant to sub-paragraph (3)(c)—
- (a) until a period of at least three months has elapsed since the date of the dismissal of the person concerned; or

⁽³²⁾ 1986 c. 45. Schedule 4A was inserted by section 257 of, and Schedule 2 to the Enterprise Act 2002 (c. 40).

⁽³³⁾ Schedule B1 was inserted by section 248 of, and Schedule 16 to, the Enterprise Act 2002.

⁽³⁴⁾ 1990 c. 40.

⁽³⁵⁾ 1986 c. 46 as amended by the Insolvency Act 2000 (c. 39).

⁽³⁶⁾ S.I.1986/1032 (N.I. 6).

⁽³⁷⁾ 1986 c. 45.

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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 his dismissal, until proceedings before that tribunal or court are concluded,

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

(6) A relevant body shall not terminate the agreement pursuant to sub-paragraph (3)(g) where the relevant body is satisfied that the conviction does not make the person unsuitable to be—

- (a) a party to the agreement; or
 - (b) in the case of an agreement with a qualifying body—
 - (i) a person legally and beneficially owning a share in the qualifying body, or
 - (ii) a director or secretary of the qualifying body,
- as the case may be.

Termination by the relevant body where there is a serious risk to the safety of patients or risk of financial loss to the relevant body

106. The relevant body may serve notice in writing on the contractor terminating the agreement forthwith or with effect from such date as may be specified in the notice if—

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

Termination by the relevant body: remedial notices and breach notices

107.—(1) Where a contractor has breached the agreement other than as specified in paragraphs 103 to 106 and the breach is capable of remedy, the relevant body shall, before taking any action it is otherwise entitled to take by virtue of the agreement, 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 relevant body 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 relevant body 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 relevant body is satisfied that the contractor has not taken the required steps to remedy the breach by the end of the notice period, the relevant body may terminate the agreement with effect from such date as the relevant body may specify in a further notice to the contractor.

(5) Where a contractor has breached the agreement other than as specified in paragraphs 103 to 106 and the breach is not capable of remedy, the relevant body 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 agreement resulting in either a remedial notice or a further breach notice,

the relevant body may serve notice on the contractor terminating the agreement with effect from such date as may be specified in that notice.

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

(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 relevant body may withhold or deduct monies which would otherwise be payable under the agreement in respect of that obligation which is the subject of the default.

Termination by the relevant body: additional provisions specific to agreements with qualifying bodies

108. Where a party to the agreement is a qualifying body, if the relevant body becomes aware that the qualifying body is carrying on any business which the relevant body considers to be detrimental to the contractor's performance of its obligations under the agreement—

- (a) the relevant body shall be entitled to give notice to the contractor requiring that the qualifying body 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 relevant body that the qualifying body has ceased carrying on that business by the end of the notice period, the relevant body may, by a further written notice, terminate the agreement forthwith or from such date as may be specified in the notice.

Agreement sanctions

109.—(1) In this paragraph and paragraph 110, “agreement sanction” means—

- (a) termination of specified reciprocal obligations under the agreement;
- (b) suspension of specified reciprocal obligations under the agreement for a period of up to six months; or
- (c) withholding or deducting monies otherwise payable under the agreement.

(2) Where the relevant body is entitled to terminate the agreement pursuant to paragraph 104, 105, 106, 107(4) or (6) or 108, it may instead impose any of the agreement sanctions if the relevant body is reasonably satisfied that the agreement sanction to be imposed is appropriate and proportionate to the circumstances giving rise to the relevant body's entitlement to terminate the agreement.

(3) If the relevant body decides to impose an agreement sanction, it must notify the contractor of the agreement 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.

(4) Subject to paragraph 110, the relevant body shall not impose the agreement sanction until at least 28 days after it has served notice on the contractor pursuant to sub-paragraph (3) unless the relevant body 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.

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(5) Where the relevant body imposes an agreement sanction, the relevant body shall be entitled to charge the contractor the reasonable costs of additional administration that the relevant body has incurred in order to impose, or as a result of imposing, the agreement sanction.

Agreement sanctions and the NHS dispute resolution procedure

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

(2) If the contractor refers the dispute relating to the agreement sanction to the NHS dispute resolution procedure within 28 days beginning on the date on which the relevant body served notice on the contractor in accordance with paragraph 109(4) (or such longer period as may be agreed in writing with the relevant body), and notifies the relevant body in writing that it has done so, the relevant body shall not impose the agreement sanction unless—

- (a) there has been a determination of the dispute pursuant to paragraph 95 and that determination permits the relevant body to impose the agreement 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 relevant body shall be entitled to impose the agreement sanction forthwith.

(4) If the relevant body is satisfied that it is necessary to impose the agreement 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 relevant body shall be entitled to impose the agreement sanction forthwith, pending the outcome of that procedure.

Termination and the NHS dispute resolution procedure

111.—(1) Where the relevant body is entitled to serve written notice on the contractor terminating the agreement pursuant to paragraph 104, 105, 106, 107(4) or (6) or 108, the relevant body shall, in the notice served on the contractor pursuant to those provisions, specify a date on which the agreement terminates that is not less than 28 days after the date on which the relevant body has served that notice on the contractor unless sub-paragraph (2) applies.

(2) This sub-paragraph applies if the relevant body 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 with sub-paragraph (1) where the exception in sub-paragraph (2) does 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 relevant body in writing that it has done so, the agreement 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 agreement shall only terminate if and when—

- (a) there has been a determination of the dispute pursuant to paragraph 95 and that determination permits the relevant body to terminate the agreement; or

(b) the contractor ceases to pursue the NHS dispute resolution procedure, whichever is the sooner.

(5) If the relevant body is satisfied that it is necessary to terminate the agreement 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 relevant body shall be entitled to confirm by written notice to be served on the contractor, that the agreement will nevertheless terminate at the end of the period of the notice it served pursuant to paragraph 104, 105, 106, 107(4) or (6) or 108.

PART 9

MISCELLANEOUS

Clinical governance

112.—(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 the system of clinical governance.

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

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

Insurance

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

(2) The contractor shall not sub-contract its obligations to provide clinical services under the agreement 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 it is held by an employee of its in connection with clinical services which that employee provides under the agreement or, as the case may be, sub-contract.

114. 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 agreement which are not covered by the insurance referred to in paragraph 113(1).

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—

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- (i) the relevant body,
- (ii) where the relevant body is a Primary Care Trust, the relevant Strategic Health Authority, or
- (iii) the Secretary of State.

Third party rights

116. The agreement shall not create any right enforceable by any person not a party to it.

Gifts

- 117.**—(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 agreement; 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 agreement is with a qualifying body—
 - (i) any person legally and beneficially owning a share in the body, or
 - (ii) a director or secretary of the body;
 - (c) any person employed by the contractor for the purposes of the agreement;
 - (d) any general medical practitioner engaged by the contractor for the purposes of the agreement;
 - (e) any spouse of a contractor (where the contractor is an individual) or of a person specified in paragraphs (b) to (d); or
 - (f) any person (whether or not of the opposite sex) whose relationship with a contractor (where the contractor is an individual) or with a person specified in paragraphs (b) to (d) 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 (f).
- (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) what the gift is;

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- (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 relevant body on request.