DIRECTIONS

THE NATIONAL HEALTH SERVICE ACT 1977

The Primary Medical Services (Directed Enhanced Services) (England) Directions 2006

The Secretary of State gives the following directions in exercise of the powers conferred by sections 17 and 126(4) of the National Health Service Act 1977(**a**):

Citation, commencement and application

1.—(1) These Directions may be cited as the Primary Medical Services (Directed Enhanced Services) (England) Directions 2006 and shall come into force on 1st July 2006.

(2) These Directions are given to Primary Care Trusts in England and apply in relation to England only.

Interpretation

2. In these Directions—

"the Act" means the National Health Service Act 1977;

"bank holiday" has the same meaning as in the National Health Service (General Medical Services) Regulations 2004(**b**);

"general practitioner" means a medical practitioner whose name is included in a medical performers list prepared by a Primary Care Trust under regulation 3 of the National Health Service (Performers Lists) Regulations 2004(**c**);

"GMS contractor" means a person with whom a Primary Care Trust is entering or has entered into a general medical services contract;

"health care professional" means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(**d**);

"PMS contractor" means a person with whom a Primary Care Trust is entering or has entered into section 28C arrangements which require the provision by that person of primary medical services;

"primary medical services contract" means—

(a) a general medical services contract;

(b) section 28C arrangements which require the provision of primary medical services; or

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(**a**) 1977 c.49. Section 17 of the 1977 Act is as substituted by the Health Act 1999 (c.8) ("the 1999 Act"), section 12(1), and thereafter amended by the Health and Social Care Act 2001 (c.15), Schedule 5, paragraph 5(3), and the National Health Service Reform and Health Care Professions Act 2002 (c.17) ("the 2002 Act"), Schedule 1, paragraph 7. Section 126(4) of the 1977 Act was amended by the National Health Service and Community Care Act 1990 (c.19), section 65(2). As regards Wales, the functions of the Secretary of State under the 1977 Act were transferred to the National Assembly for Wales by virtue of article 2 of, and Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672), as amended by section 66(5) of the 1999 Act and as read with section 40(1) of the 2002 Act.

(**b**) 2004/291 as amended by S.I. 2004/2694, 2005/893 and 3315 and 2006/1501.

(**c**) S.I. 2004/585; amended by S.I. 2004/2694, 2005/502, 893 and 3491 and 2006/635 and 3185.

(**d**) 2002 c.17.

(c) contractual arrangements for the provision of primary medical services under section 16CC(2)(b) of the Act (primary medical services);

"primary medical services contractor" means—

(a) a GMS or PMS contractor; or

(b) a person with whom a Primary Care Trust is making or has made contractual arrangements for the provision of primary medical services under section 16CC(2)(b) of the Act;

"Statement of Financial Entitlements" means any directions given by the Secretary of State under section 28T of the Act(**a**) (GMS contracts: payments); and

"working day" means any day apart from Saturday, Sunday, Christmas Day, Good Friday or a bank holiday.

Establishment etc of directed enhanced services schemes

3.—(1) Each Primary Care Trust must exercise its functions under section 16CC of the Act of providing primary medical services within its area, or securing their provision within its area, by (as part of its discharge of those functions) establishing (if it has not already done so), operating and, as appropriate, revising the following schemes for its area—

(a) a Towards Practice Based Commissioning Scheme, the underlying purpose of which is to encourage GMS and PMS contractors to engage in practice based commissioning;

(b) an Improved Access Scheme, the underlying purpose of which is to improve patient access to primary medical services, and which will comprise or include arrangements for—

(i) allowing patients requiring routine appointments to consult a general practitioner, on request, to be able to consult a general practitioner, face-to-face or by telephone, by the end of the second working day after the day on which the request was made,

(ii) allowing patients requiring routine appointments to consult a general practitioner to be able to book such appointments more than 48 hours in advance,

(iii) allowing patients who contact the contractor's premises by telephone to be able to do so without difficulty, and

(iv) allowing patients, as far as is possible, to be able to consult the health care professional that they request on making the appointment;

(c) an Information Management and Technology Scheme, the underlying purpose of which is to encourage and facilitate the adoption by GMS and PMS contractors of information management and technology systems which will support the delivery of the National Programme for Information Technology;

(d) a Choice and Booking Scheme, the underlying purpose of which is to encourage GMS and PMS contractors to—

(i) offer patients who they are referring for a first consultant outpatient appointment under the Act a choice of provider; and

(ii) use the national Choose and Book system when booking a first consultant outpatient appointment under the Act;

(e) a Childhood Immunisation Scheme, the underlying purpose of which is to ensure that patients in its area—

(i) who have passed their second birthday but not yet their third are able to benefit from the recommended immunisation courses (i.e. those that have been recommended nationally and by the World Health Organisation) for protection against—

(aa) diphtheria, tetanus, poliomyelitis, pertussis and Haemophilus influenzae type B (HiB), and

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(**a**) Section 28T was inserted by the Health and Social Care (Community Health and Standards) Act 2003 (c.43), section 175.

(bb) measles/mumps/rubella, or

(ii) who have passed their fifth birthday but not yet their sixth birthday are able to benefit from the recommended reinforcing doses (i.e. those that have been recommended nationally and by the World Health Organisation) for protection against diphtheria, tetanus, acellular pertussis and poliomyelitis;

(f) an Influenza and Pneumococcal Immunisation Scheme, the underlying purposes of which is to ensure that patients in its area who are at-risk of influenza or pneumococcal infection are offered immunisation against these infections;

(g) a Violent Patients Scheme, the underlying purpose of which is to ensure that there are sufficient arrangements in place to provide primary medical services to patients that have been subject to immediate removal from a patient list of a primary medical services contractor because of an act or threat of violence; and

(h) a Minor Surgery Scheme, the underlying purpose of which to ensure that a wide range of minor surgical procedures are made available as part of the primary medical services provided within the Primary Care Trust's area.

(2) Before entering into any arrangements with a primary medical services contractor as part of one of the Schemes mentioned in paragraph (1), a Primary Care Trust must satisfy itself that the contractor with which it is proposing to enter into those arrangements—

(a) is capable of meeting its obligations under those arrangements including under any plan agreed under those arrangements; and

(b) in particular, has the necessary facilities, equipment and properly trained and qualified general practitioners, health care professionals and staff to carry out those obligations,

and nothing in these directions shall be taken as requiring a PCT to enter into such arrangements with a contractor if it has not been able to satisfy itself in this way about the contractor.

Towards Practice Based Commissioning Scheme

4.—(1) As part of its Towards Practice Based Commissioning Scheme, each Primary Care Trust must, subject to paragraph (2), offer to each GMS contractor in its area, and each PMS contractor in its area for which it holds a list of registered patients, the opportunity to enter into arrangements in respect of the financial year 2006/2007, thereby affording the contractor a reasonable opportunity to participate in the scheme during the financial year 2006/2007.

(2) A Primary Care Trust is not required to offer to enter into arrangements with any GMS or PMS contractor if it has, prior to the coming into force of these Directions, entered into any arrangement with that GMS or PMS contractor the purpose of which was to encourage the contractor to engage in practice based commissioning and which the Primary Care Trust, having consulted the contractor, is satisfied meets the same or broadly similar standards and objectives as the scheme the Primary Care Trust must offer under these Directions.

(3) If a Primary Care Trust has entered into arrangements with a contractor as set out in paragraph (2), it must, prior to 31st August 2006, review those arrangements and, subject to the agreement of the contractor, vary the terms of the agreement relating to those arrangements as follows—

(a) if the arrangements would otherwise terminate prior to 31st March 2007, the terms of the agreement must be extended to 31st March 2007;

(b) if the arrangements would otherwise extend beyond 31st March 2007, the terms of the agreement must be reduced to 31st March 2007;

(c) if the financial terms are less favourable than those that would be available under the scheme made available under these Directions and the Statement of Financial Entitlement, the financial terms are to be varied so as to be equivalent, as regards the financial year 2006/2007, to the financial terms that would apply to a scheme made available under these Directions and Statement of Financial Entitlement; and

(d) if the requirements imposed on either the Primary Care Trust or the contractor are not equivalent to those that would be imposed under a scheme made available under these Directions and Statement of Financial Entitlement, the requirements must be varied so as to impose requirements of an equivalent standard,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the terms of any agreement revised in accordance with the requirements of this paragraph comprise part of the contractor's contract and the requirements of the agreement revised in accordance with the requirements of this paragraph are conditions of the contract.

(4) The Primary Care Trust shall not be required to enter into arrangements pursuant to paragraph (1) with a contractor unless the contractor has indicated in writing to the Primary Care Trust before 1st February 2007 that it wishes to enter into arrangements, and thereafter the arrangements under paragraph (1) shall be entered into before 15th February 2007.

(5) The arrangements must provide—

(a) for the contractor to provide a plan by the date specified in the arrangements agreed between the contractor and the Primary Care Trust, or within a reasonable period where the arrangements do not specify a date, covering the matters set out in paragraph (6), for the Primary Care Trust to approve;

(b) for the Primary Care Trust to assist the contractor in developing the plan referred to in sub-paragraph (a) by providing the contractor with—

(i) information held by the Primary Care Trust on the matters set out in the Schedule to these Directions; and

(ii) information on any other matters the Primary Care Trust and the contractor may agree between them,

subject always to the Primary Care Trust complying with its obligations relating to data protection and patient and commercial confidentiality;

(c) for the Primary Care Trust to consider the plan with a view to agreeing it and not to withhold its agreement unreasonably;

(d) for the contractor to implement the agreed plan in so far as it places obligations upon it; and

(e) in the case of PMS contractors, for the inclusion of the amount of the payments to be made to the contractor for agreeing and meeting its obligations under the arrangements, and those payments must comprise—

(i) an initial payment in respect of the plan referred to in sub-paragraph (a), payable once the plan has been agreed by the Primary Care Trust in accordance with sub-paragraph (c), and

(ii) a reward payment, payable when the Primary Care Trust is satisfied that the contractor has achieved all the agreed targets and objectives set out in the plan in accordance with paragraph (6)(g) and (j),

and in determining the appropriate level of those payments the Primary Care Trust must have regard to the amounts of payments under section 7A of the Statement of Financial Entitlements.

(6) The draft plan must include—

(a) the name and practice address of the contractor or contractors participating in the plan;

(b) arrangements under which any contractor which is party to a joint plan may withdraw from such collaboration, which must include—

(i) a provision that no such withdrawal may take place after 31st January 2007; and

(ii) the time limit, which should not exceed 6 weeks, within which any contractor withdrawing from such collaboration shall agree an individual plan with the Primary Care Trust if it wishes to continue to participate in the Towards Practice Based Commissioning Scheme;

(c) details of the clinical lead;

(d) the baseline of referrals for 2005/2006 or the baseline of admissions by specialty for 2005/2006 (or both);

(e) details of the services to be covered by the specified budget in respect of which the contractor will make recommendations to the Primary Care Trust;

(f) details of the specialties and services which the contractor is to redesign in order to improve services to patients;

(g) details of the specific and measurable targets and objectives that the contractor is to achieve;

(h) the method by which the quality of any redesigned services is to be demonstrated;

(i) the method by which the quality of any redesigned services is to be assured;

(j) the threshold for meeting any objectives in the plan which will qualify the contractor for the award of the reward payment;

(k) the arrangements for the provision of information by the Primary Care Trust and by the contractor; and

(l) the arrangements for the monitoring of the plan by the Primary Care Trust.

(7) The arrangements shall be incorporated into the contractor's primary medical services contract.

Improved Access Scheme

5.—(1) As part of its Improved Access Scheme, each Primary Care Trust must offer to each GMS contractor in its area, and each PMS contractor in its area for which it holds a list of registered patients, the opportunity to enter into arrangements in respect of the financial year 2006/2007, thereby affording the contractor a reasonable opportunity to participate in the scheme during the financial year 2006/2007.

(2) The Primary Care Trust shall not be required to enter into arrangements pursuant to paragraph (1) with a contractor unless the contractor has indicated in writing to the Primary Care Trust before 1st February 2007 that it wishes to enter into arrangements, and thereafter the arrangements under paragraph (1) shall be entered into before 15th February 2007.

(3) The arrangements must provide—

(a) for the contactor to provide a plan by the date specified in the arrangements agreed between the contractor and the Primary Care Trust, or within a reasonable period where the arrangements do not specify a date, covering the matters set out in paragraph (4), for the Primary Care Trust to approve;

(b) for the Primary Care Trust to consider the plan with a view to agreeing it and not to withhold its agreement unreasonably;

(c) for the contractor to implement the agreed plan in so far as it places obligations upon it;

(d) for the contractor to co-operate with the Primary Care Trust in facilitating the carrying out of the national patient experience survey in respect of the contractor's practice; and

(e) in the case of PMS contractors, for the inclusion of the amount of the payments to be made to the contractor for agreeing and meeting its obligations under the arrangements, and those payments must comprise—

  (i) an initial payment in respect of the plan referred to in sub-paragraph (a) payable once the plan has been agreed by the Primary Care Trust in accordance with sub-paragraph (b);

  (ii) an initial payment in respect of the contractor giving a written undertaking to participate in, and to continue participation in, the Primary Care Trust's monthly Primary Care Access Survey at least up to 31st March 2007; and

  (iii) a reward payment, payable following the end of the financial year 2006/2007 and based on the results of the national patient experience survey,

and in determining the appropriate level of those payments the Primary Care Trust must have regard to the amounts of payments under section 7B of the Statement of Financial Entitlements.

(4) The plan —

(a) must include details of the actions the contractor proposes to take in order to—

(i) allow patients requiring routine appointments to consult a general practitioner, on request, to be able to consult a general practitioner, face-to-face or by telephone, by the end of the second working day after the day on which the request was made,

(ii) allow patients requiring routine appointments to consult a general practitioner to be able to book such appointments more than 48 hours in advance, and

(iii) allow patients who contact the contractor's premises by telephone to be able to do so without difficulty;

(b) must include the arrangements for the provision of information by the Primary Care Trust and by the contractor;

(c) must include the arrangements for the monitoring of the plan by the Primary Care Trust; and

(d) may include a written commitment signed on behalf of the contractor to participate in, and to continue participation in, the monthly Primary Care Access Survey at least up to 31st March 2007.

(5) The arrangements shall be incorporated into the contractor's primary medical services contract.

Information Management and Technology Scheme

6.—(1) As part of its Information Management and Technology Scheme, each Primary Care Trust must offer to each GMS contractor in its area, and each PMS contractor in its area for which it holds a list of registered patients, the opportunity to enter into arrangements in respect of the financial year 2006/2007, thereby affording the contractor a reasonable opportunity to participate in the scheme during the financial year 2006/2007.

(2) The Primary Care Trust shall not be required to enter into arrangements pursuant to paragraph (1) with a contractor unless the contractor has indicated in writing to the Primary Care Trust before 1st February 2007 that it wishes to enter into arrangements, and thereafter the arrangements under paragraph (1) shall be entered into before 15th February 2007.

(3) The arrangements must provide—

(a) for the contactor to provide a plan by the date specified in the arrangements agreed between the contractor and the Primary Care Trust, or within a reasonable period where the arrangements do not specify a date, covering the matters set out in paragraph (4), for the Primary Care Trust to approve;

(b) for the Primary Care Trust to consider the plan with a view to agreeing it and not to withhold its agreement unreasonably;

(c) for the contractor to implement the agreed plan in so far as it places obligations upon it; and

(d) in the case of PMS contractors, for the inclusion of the amount of the payments to be made to the contractor for agreeing and meeting its obligations under the arrangements, and those payments must comprise —

(i) an initial payment in respect of the plan referred to in sub-paragraph (a) payable once the plan has been agreed by the Primary Care Trust in accordance with sub-paragraph (b),

(ii) a payment on achieving the standard of data accreditation required by Connecting for Health necessary for uploading electronic patient summaries,

(iii) a payment on demonstrating to the Primary Care Trust—

(aa) that it has an acceptable system of accurate electronic maintenance of patients' addresses; and

(bb) that it is using the most up to date release of the electronic prescription system (EPS) system software that its system can support and that its staff are appropriately trained in the use of this software, it has appropriate standard operating procedures and its patient information leaflet includes relevant information concerning the issue and collection of prescriptions, and

(iv) a payment on successfully migrating to a Connecting for Health accredited hosted system,

and in determining the appropriate level of those payments the Primary Care Trust must have regard to the amounts of payments under section 7C of the Statement of Financial Entitlements.

(4) The plan must include—

(a) the name of the person within the practice ("the practice lead") who will liaise with Connecting for Health on matters relating to the Information Management and Technology Scheme;

(b) the name of the person within the practice who will undertake the role of "Caldicott Guardian";

(c) a training needs assessment and linked training plan for each member of the practice team involved with the operation of IT systems;

(d) an undertaking on the part of the contractor to implement any training plans drawn up under sub-paragraph (c);

(e) evidence of compliance by the contractor with good information governance practice, including but not limited to—

(i) the use of clauses on confidentiality in contracts of employment and contracts for services,

(ii) appropriate training arrangements, and

(iii) compliance with statutory requirements and any NHS guidance and requirements relating to data protection, patient confidentiality, the proper use of information technology and related matters;

(f) a requirement that the contractor—

(i) ensures that the role of practice lead is always undertaken by a member of the practice staff and informs the Primary Care Trust of any change in the identity of the person undertaking that role, and

(ii) ensures that the role of Caldicott Guardian is always undertaken by a member of the practice staff and informs the Primary Care Trust of any change in the identity of the person undertaking that role;

(g) a requirement that the contractor maintains a written record of the training undertaken by each member of the practice staff involved with the operation of IT systems and makes that record available to the Primary Care Trust on its request;

(h) a requirement that the contractor maintains a written record of in-house training events undertaken by the contractor including but not limited to—

(i) induction training of new staff, including locum and relief staff, and

(ii) an attendance record signed by those attending the event;

(i) a requirement that the contractor work towards achieving the standard of data accreditation required by NHS Connecting for Health necessary for uploading electronic patient summaries and the details of the steps the contractor proposes to take in order to achieve that standard;

(j) a requirement that the contractor work towards achieving a system of accurate electronic maintenance of patients' addresses and the details of the steps the contractor proposes to take in order to achieve that standard;

(k) a requirement that the contractor work towards participation in the Electronic Prescription Service programme, and the details of the steps the contractor proposes to take in order to achieve that target which should include but are not limited to—

(i) arranging appropriate training for each member of the practice team involved in the operation of IT systems,

(ii) identifying and carrying out necessary changes in working practices,

(iii) reviewing and where necessary amending standard operating procedures,

(iv) using EPS Release 1 software, and

(v) where available and permissible, using EPS Release 2 Software;

(l) a requirement that the contractor work toward achieving a standard that will permit it to migrate to the N3 network and details of the steps the contractor proposes to take in order to achieve that standard, which should include but is not limited to enabling the upgrade of its computer hardware to a nationally specified standard as set by Connecting for Health in consultation with the Joint GPC/RCGP IT Committee, and

(m) a requirement that the contractor ensures that—

(i) every member of the contactor's staff who has access to the contractor's computer system is authenticated as a user and is registered with a Smart card for use on that system and trained in the use of such Smart card, and

(ii) there is in place within the practice, with the support as appropriate of the Primary Care Trust, an appropriate system for authentication, registration and training of new members of staff with regard to Smart cards;

(n) the arrangements for the provision of information by the Primary Care Trust and by the contractor; and

(o) the arrangements for the monitoring of the plan by the Primary Care Trust.

(5) The arrangements shall be incorporated into the contractor's primary medical services contract.

Choice and Booking Scheme

7.—(1) As part of its Choice and Booking Scheme, each Primary Care Trust must offer to each GMS contractor in its area, and each PMS contractor in its area for which it holds a list of registered patients, the opportunity to enter into arrangements in respect of the financial year 2006/2007, thereby affording the contractor a reasonable opportunity to participate in the scheme during the financial year 2006/ 2007.

(2) The Primary Care Trust shall not be required to enter into arrangements pursuant to paragraph (1) with a contractor unless the contractor has indicated in writing to the Primary Care Trust before 1st February 2007 that it wishes to enter into arrangements, and thereafter the arrangements under paragraph (1) shall be entered into before 15th February 2007.

(3) The arrangements that a Primary Care Trust enters into with a GMS or PMS contractor as part of its Choice and Booking Scheme may be for—

(a) the choice element of the Scheme only;

(b) the Choose and Book element of the scheme only; or

(c) both the choice and the Choose and Book elements of the scheme (in this direction referred to as "Choice and Booking").

(4) The arrangements that a Primary Care Trust enters into with a GMS or PMS contractor for Choice and Booking must include—

(a) a written commitment by the contractor—

(i) to support patients in making an informed choice of the provider to which they are to be referred, and

(ii) to use the national Choose and Book system in making such referrals;

(b) a requirement that the contractor ensures that the patient is informed of his option to choose the provider to which they are to be referred;

(c) a requirement that the contractor makes available to a patient to whom a choice is being offered information and support to help him make an informed choice which should include but is not limited to—

(i) the provision of a shortlist of clinically appropriate providers,

(ii) discussion with the patient regarding any relevant clinical aspects of the choices available, and

(iii) discussion with the patient regarding any other relevant matters relating to the choices available or information to the patient as to where he can obtain that information;

(d) a requirement that the contractor make available to a patient information when making his decision, which must where appropriate include but is not limited to—

(i) offering a patient information booklet as provided by the Primary Care Trust, and

(ii) providing information about outpatient waiting time for the relevant specialty;

(e) a requirement that the contractor co-operate with the Primary Care Trust in any review intended to assure the quality of the local choice process from a patient's perspective;

(f) a requirement that the contractor—

(i) ensures that every patient whose referral is being dealt with using the Choose and Book system is given a unique booking reference number and a patient password before leaving the practice following the consultation with the general practitioner at which the need for a first consultant outpatient appointment is identified,

(ii) ensures that the patient is given, at the consultation with the general practitioner at which the need for a first consultant outpatient appointment is identified, either—

(aa) an appointment with his chosen provider; or

(bb) written information about any action the patient must take in order to complete the process of making his choice and to make a booking, and

(iii) subject to paragraph (5), within time-limits agreed with the Primary Care Trust, and set out in the arrangements, generates and attaches a referral letter to any appointment request, either manually or by using a GP integrated IT system;

(g) a requirement that the contractor co-operate with the Primary Care Trust in facilitating the carrying out of the national patient experience survey in respect of the contractor's practice;

(h) the arrangements for the provision of information by the Primary Care Trust and by the contractor;

(i) the arrangements for the monitoring of the arrangements by the Primary Care Trust; and

(j) in the case of PMS contractors, the amount of the payments to be made to the contractor for agreeing and meeting its obligations under the arrangements, and those payments must comprise—

(i) an initial payment for agreeing with the Primary Care Trust to provide patients with the opportunity to make an informed choice in choosing a provider for a first consultant outpatient appointment under the Act,

(ii) a reward payment for achieving a specified standard in providing patients with the opportunity to make an informed choice in choosing a provider for a first consultant outpatient appointment under the Act,

(iii) an initial payment for agreeing to use the national Choose and Book system, and

(iv) a reward payment for using the national Choose and Book system to a specified standard,

and in determining the appropriate level of those payments the Primary Care Trust must have regard to the amounts of payments under section 7D of the Statement of Financial Entitlements,

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

(5) The time-limits to be agreed by the Primary Care Trust for a referral for an appointment and referred to in sub-paragraph (4)(f)(iii) must provide that—

(a) in the case of a referral for a patient who has or is suspected of having cancer or where the referral is urgent, the referral must take place within one working day; and

(b) in the case of other referrals, the referral must take place within three working days unless the contractor has a good reason for not being able to make a referral within the agreed time-limit.

(6) The arrangements that a Primary Care Trust enters into with a GMS or PMS contractor for Choice element of the scheme only must comply with paragraph (4)(a)(i), (b) to (e), (g) to (i) and (j)(i) and (ii), and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the arrangements comprise part of the contractor's contract and the requirements of the arrangements are conditions of the contract.

(7) The arrangements that a Primary Care Trust enters into with a GMS or PMS contractor for Choose and Book element of the scheme only must comply with paragraph (4)(a)(ii), (f), (h), (i), and (j)(iii) and (iv) and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the arrangements comprise part of the contractor's contract and the requirements of the arrangements are conditions of the contract.

Childhood Immunisation Scheme

8.—(1) As part of its Childhood Immunisation Scheme, each Primary Care Trust must, each financial year, offer to enter into arrangements with each GMS or PMS contractor in its area, unless—

(a) it already has such arrangements with the contractor in respect of that financial year; or

(b) in the case of a GMS contractor, the contractor is not providing the childhood immunisations and pre-school boosters additional service under its general medical services contract,

thereby affording the contractor a reasonable opportunity to participate in the Scheme during that financial year.

(2) The plan setting out the arrangements that a Primary Care Trust enters into, or has entered into, with any primary medical services contractor as part of its Childhood Immunisation Scheme must, in respect of each financial year to which the plan relates, include—

(a) a requirement that the contractor—

(i) develops and maintains a register (its "Childhood Immunisation Scheme Register", which may comprise electronically tagged entries in a wider computer database) of all the children for whom the contractor has a contractual duty to provide childhood immunisation and pre-school booster services (who may already have been immunised, by the contractor or otherwise, or to whom the contractor has offered or needs to offer immunisations),

(ii) undertakes to offer the recommended immunisations referred to in direction 3(b) to the children on its Childhood Immunisation Scheme Register (with the aim of maximising uptake in the interests of patients, both individually and collectively), and

(iii) undertakes to record the information that it has in Childhood Immunisation Scheme Register using any applicable national Read codes;

(b) a requirement that the contractor—

(i) develops a strategy for liasing with and informing parents or guardians of children on its Childhood Immunisation Scheme Register about its immunisation programme with the aim of improving uptake, and

(ii) provides information on request to those parents or guardians about immunisation;

(c) a requirement that the contractor takes all reasonable steps to ensure that the lifelong medical records held by a child's general practitioner are kept up-to-date with regard to the child's immunisation status, and in particular include—

(i) any refusal of an offer of vaccination,

(ii) where an offer of vaccination was accepted—

(aa) details of the consent to the vaccination or immunisation (where a person has consented on a child's behalf, that person's relationship to the child must also be recorded),

(bb) the batch number, expiry date and title of the vaccine,

(cc) the date of administration of the vaccine,

(dd) where two vaccines are administered in close succession, the route of administration and any injection site of each vaccine,

(ee) any contraindications to the vaccination or immunisation,

(ff) any adverse reactions to the vaccination or immunisation;

(d) a requirement that the contractor ensures that any health care professional who is involved in administering a vaccine has—

(i) any necessary experience, skills and training with regard to the administration of the vaccine, and

(ii) training with regard to the recognition and initial treatment of anaphylaxis;

(e) a requirement that the contractor ensures that—

(i) all vaccines are stored in accordance with the manufacturer's instructions, and

(ii) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken from that thermometer on all working days;

(f) a requirement that the contractor supply its Primary Care Trust with such information as it may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the plan;

(g) arrangements for an annual review of the plan which shall include—

(i) an audit of the rates of immunisation, which must also cover any changes to the rates of immunisation, and

(ii) an analysis of the possible reasons for any changes to the rates of immunisation; and

(h) in the case of contractors that are not GMS contractors, the payment arrangements for the contractor, which must comprise target payments to the contractor where the contractor—

(i) meets its obligations under the plan, and

(ii) meets, in respect of the children on the contractor's Childhood Immunisation Scheme Register, immunisation levels designed to ensure adequate protection, both for individual patients and for the public, against the infectious diseases against which immunisation is being offered (and the Primary Care Trust must take no account of exception reporting in its calculations of target payments),

and in determining the appropriate level of those target payments, the Primary Care Trust must have regard to the target payments and the targets rewarded under Section 8 of the Statement of Financial Entitlements,

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

Influenza and Pneumococcal Immunisation Scheme

9. As part of its Influenza and Pneumococcal Immunisation Scheme, each Primary Care Trust may enter into arrangements with any primary medical services contractor, but where it does so, the plan setting out the arrangements that a Primary Care Trust enters into, or has entered into, with the primary medical services contractor must, in respect of each financial year to which the plan relates, include—

- (a) a requirement that the contractor develops and maintains a register (its "Influenza and Pneumococcal Scheme Register", which may comprise electronically tagged entries in a wider computer database) of all the at-risk patients to whom the contractor is to offer immunisation against influenza or pneumococcal infection, and for these purposes a patient is at risk of—
  - (i) influenza infection if he is—
    - (aa) aged 65 or over at the end of that financial year,
    - (bb) suffering from chronic respiratory disease (including asthma), chronic heart disease, chronic renal disease, immuno-suppression due to disease or treatment, or diabetes mellitus,
    - (cc) living in long-stay residential or nursing homes or other long-stay health or social care facilities, or
  - (ii) pneumococcal infection if he is aged 65 or over at the end of the financial year;
- (b) a requirement that the contractor undertakes—
  - (i) to offer immunisations against those infections to those at risk patients, and with immunisations against influenza infection—
    - (aa) to make that offer during the period from 1st August to 31st March in that financial year, but
    - (bb) to concentrate the immunisation programme during the period from 1st September to 31st January in that financial year, and
  - (ii) to record the information that it has in its Influenza and Pneumococcal Immunisation Register using any applicable national Read codes;
- (c) a requirement that the contractor develops a proactive and preventative approach to offering these immunisations by adopting robust call and reminder systems to contact at-risk patients, with the aims of—
  - (i) maximising uptake in the interests of at-risk patients, and
  - (ii) meeting any public health targets in respect of such immunisations;
- (d) a requirement that the contractor takes all reasonable steps to ensure that the lifelong medical records held by an at-risk patient's general practitioner are kept up-to-date with regard to his immunisation status, and in particular include—
  - (i) any refusal of an offer of vaccination,
  - (ii) where an offer of vaccination was accepted—
    - (aa) details of the consent to the vaccination or immunisation (where a person has consented on an at-risk patient's behalf, that person's relationship to the at-risk patient must also be recorded),
    - (bb) the batch number, expiry date and title of the vaccine,
    - (cc) the date of administration of the vaccine,
    - (dd) where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine,

(ee) any contraindications to the vaccination or immunisation,

(ff) any adverse reactions to the vaccination or immunisation;

(e) a requirement that the contractor ensures that any health care professional who is involved in administering a vaccine has—

(i) any necessary experience, skills and training with regard to the administration of the vaccine, and

(ii) training with regard to the recognition and initial treatment of anaphylaxis;

(f) a requirement that the contractor ensures that—

(i) all vaccines are stored in accordance with the manufacturer's instructions, and

(ii) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken from that thermometer on all working days;

(g) a requirement that the contractor supply its Primary Care Trust with such information as it may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the plan; and

(h) the payment arrangements for the contractor,

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

Violent Patient Scheme

10.—(1) Each Primary Care Trust must consult the local medical committee (if any) for its area about any proposals it has to establish or revise a Violent Patients Scheme.

(2) As part of its Violent Patients Scheme, each Primary Care Trust may enter into arrangements with any primary medical services contractor, but where it does so, the plan setting out those arrangements must provide, in respect of each financial year to which the plan relates, for the payment arrangements for the contractor agreeing and meeting its obligations under the plan.

Minor Surgery Scheme

11. As part of its Minor Surgery Scheme, each Primary Care Trust may enter into arrangements with any primary medical services contractor, but where it does so, the plan setting out the arrangements that a Primary Care Trust enters into, or has entered into, with the primary medical services contractor must, in respect of each financial year to which the plan relates, include—

(a) which minor surgical procedures are to be undertaken by the contractor and for which patients, and for these purposes, the minor surgical procedures that may be undertaken are any minor surgical procedures that the Primary Care Trust considers the contractor competent to provide, which may include—

(i) injections for muscles, tendons and joints,

(ii) invasive procedures, including incisions and excisions, and

(iii) injections of varicose veins and piles;

(b) a requirement that the contractor takes all reasonable steps to provide suitable information to patients in respect of whom they are contracted to provide minor surgical procedures about those procedures;

(c) a requirement that the contractor—

(i) obtains written consent to the surgical procedure before it is carried out (where a person consents on a patient's behalf, that person's relationship to the patient must be recorded on the consent form), and

(ii) takes all reasonable steps to ensure that the consent form is included in the lifelong medical records held by the patient's general practitioner;

(d) a requirement that the contractor ensures that all tissue removed by surgical procedures is sent for histological examination, unless there are acceptable reasons for not doing so;

(e) a requirement that the contractor ensures that any health care professional who is involved in performing or assisting in any surgical procedure has—

(i) any necessary experience, skills and training with regard to that procedure; and

(ii) resuscitation skills;

(f) a requirement that the contractor ensures that it has appropriate arrangements for infection control and decontamination in premises where surgical procedures are undertaken, and for these purposes, the Primary Care Trust may stipulate—

(i) the use of sterile packs from the local Central Sterile Service Departments, disposable sterile instruments, or approved sterilisation procedures,

(ii) the use of particular infection control policies in relation to, for example, the handling of used instruments and excised specimens, and the disposal of clinical waste;

(g) a requirement that the contractor ensures that all records relating to all surgical procedures are maintained in such a way—

(i) that aggregated data and details of individual patients are readily accessible for lawful purposes, and

(ii) as to facilitate regular audit and peer review by the contractor of the performance of surgical procedures under the plan;

(h) a requirement that the contractor supplies its Primary Care Trust with such information as it may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the plan; and

(i) the payment arrangements for the contractor,

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

Revocations

12. The Primary Medical Services (Directed Enhanced Services) (England) Directions 2005 and the Primary Medical Services (Directed Enhanced Services) (England) (Amendment) Directions 2006 are hereby revoked.

Signed by authority of the Secretary of State for Health

Richard Armstrong
Department of Health
A member of the Senior Civil Service

29 June 2006

SCHEDULE

Direction 4(5)(b)(i)

Information the Primary Care Trust must provide to the contractor to assist the contractor in developing its plan

1. Details of national and local priorities and commitments.

2. Information known or reasonably accessible to the Primary Care Trust about the contractor's use of health services, which must include—

(a) benchmarking data covering –

(i) referral rates,
(ii) admission rates,
(iii) first outpatient consultant appointment attendances, and
(iv) follow up rates.

(b) activity and financial information for NHS and non-NHS activity, covering –

(i) elective data – inpatient and day case,
(ii) non-elective admissions including length of stay,
(iii) first outpatient appointments, and follow up appointments,
(iv) use of diagnostic tests and procedures,
(v) consultant to consultant referrals,
(vi) accident and emergency attendances,
(vii) prescribing,
(viii) community and mental health services,
(ix) primary care services, particularly essential, additional and enhanced primary medical services provided under a general medical services contract, personal medical services agreement or alternative provider medical services contract and services provided as Primary Care Trust Medical Services, and
(x) attendances at other services such as walk-in centres;

(c) information about the needs, demands and demographics of the local population in the Primary Care Trust's area.